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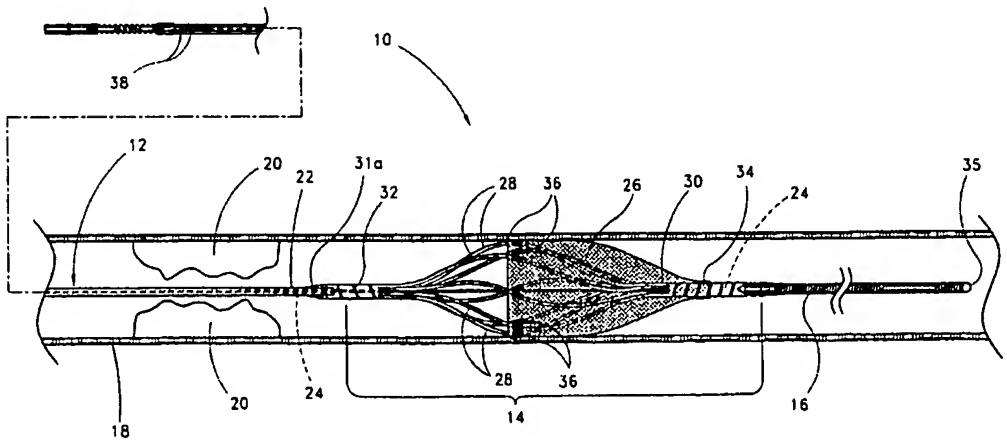
(54) Title: STRUT DESIGN FOR AN OCCLUSION DEVICE



(57) Abstract: A filter device is inserted into the blood vessel of a patient at the end of a catheter-like shaft. The filter device includes a perfusion membrane supported by struts which are disposed distally on the shaft of the device. When actuated from an adapter located outside the patient, the struts deploy into an expanded configuration, bringing the membrane into a configuration to allow blood to pass through the filter device, but trapping embolic matter within the membrane. This embolic material is removed either by aspiration or by collapsing the struts and trapping the embolic matter within the strut system for removal along with the removal of the filter device.

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STRUT DESIGN FOR AN OCCLUSION DEVICE

Background of the Invention

Field of the Invention

This invention relates generally to the field of intravascular devices for filtering emboli from blood. More specifically, this invention relates to the design of struts used in intravascular devices for filtering emboli from blood.

Description of the Related Art

Although attempts have been made to treat occlusions in the carotid arteries leading to the brain, such arteries have been very difficult to treat because of the possibility of dislodging plaque which can then enter various arterial vessels of the brain and cause permanent brain damage. Attempts to treat such occlusions with balloon angioplasty have been limited because of such dangers. In surgical treatments, such as endarterectomy, the carotid artery is slit and plaque is removed from the vessel in the slit area. Such surgical procedures, however, also entail substantial risk.

In other procedures, such as in angioplasty and in the treatment of peripheral arteries and veins, there is the possibility that the delivery of the guide wires and catheters used in such procedures may dislodge plaque. When emboli or other particulates flow downstream to occlude blood flow in smaller vessels, they can cause serious damage, such as stroke. Thus, embolization and migration of micro-emboli downstream to an end organ is a major concern of cardiologists during catheterizations.

Various vascular filters have been proposed which would contain emboli produced as a result of intravascular procedures. However, the proper deployment of such filters remains problematic. For example, if a filter expands too far, damage to the vessel can result. Further, care must be taken when performing intravascular procedures that any interruption in the blood flow is temporary and minimal.

Thus, there remains a need for new and improved apparatuses and methods which make possible the treatment of occluded vessels without endangering the patient.

Summary of the Invention

The present invention provides new and improved apparatuses and methods for filtering embolic matter from the blood stream of a patient who is undergoing vascular therapy. The apparatuses and methods prevent dislodged plaque or other particles from flowing downstream to occlude blood flow in smaller vessels where they can cause serious damage.

In one preferred embodiment of the present invention, an occlusion device is provided for trapping and containing particles in a blood vessel. The occlusion device is characterized by a shaft, a filter subassembly and a guide tip. The filter subassembly is delivered on the shaft to the location in a blood vessel distal of the region being treated. The filter subassembly is then expanded to occlude the vessel distal of the treatment site. Particles which are dislodged from the treatment site and trapped within the filter subassembly. These particles may then be removed by contracting the filter subassembly so as to contain the particles and withdrawing the device from the vessel. As an alternative or in addition to this method of particle removal, an aspiration catheter may be delivered over the shaft and used to aspirate some or all of the particles from the filter subassembly.

In one preferred embodiment, the occlusion device comprises an elongate tubular body having a proximal end and a distal end and a lumen extending therethrough. A pull wire having a proximal end and a distal end extends through the lumen of the tubular body. A filter subassembly including a plurality of struts is provided, the plurality of struts having a proximal end connected to the distal end of the elongate body and a distal end connected to the pull wire. The plurality of struts have a collapsed configuration and an expanded configuration, the collapsed configuration comprising the struts as they lie closest to the longitudinal axis of the elongate body and have the least radial extension, and said expanded configuration comprising the struts as they extend radially to their greatest extent from the longitudinal axis of the elongate body. The two configurations are selectable by displacement of the elongate body relative to the pull wire. The plurality of struts are formed from a single piece of tubing.

In another preferred embodiment of the present invention, a strut system for an occlusion device is provided. The strut system includes a support shaft, a set of struts for supporting a filter membrane, and a distal tip. The support shaft includes a plurality of concentric elongated cylindrical members, and the set of struts is adjustable from a collapsed configuration into an expanded configuration. In the collapsed configuration, the struts lie along the shaft and are suitable for delivery through the blood stream of the patient. In the expanded configuration, the struts extend radially from the shaft to span substantially the entire cross-section of the blood vessel being treated. These configurations are selected by moving one member of the shaft relative to another so as to create either a tensional or a torsional force upon the set of struts and cause them to change configuration.

In an alternate preferred embodiment of the present invention, an occlusion device is provided which includes a strut system, substantially as described above, as well as a filter membrane which is disposed upon and attached to the set of struts. The occlusion device also includes a control adapter which is used to apply tensional or torsional forces to the elongated members of the shaft of the device and actuate the motion of the struts. Alternatively, slits may be cut into the distal region of a member of the support shaft in order to integrally form the struts upon the outermost members of the shaft of the device.

A method of trapping embolic material during vascular therapy procedures forms another preferred embodiment of the present invention. In such a method, an occlusion device is delivered downstream of the therapy site within the blood stream of the patient and actuated into the expanded configuration. Once actuated, the vascular therapy is performed, and any embolic material dislodged during the therapy is trapped by the filter membrane. This material may optionally be removed from the filter as the therapy proceeds, and when the therapy is concluded, the filter is cleared of embolic matter and then retracted into its collapsed configuration and extracted from the vasculature of the patient.

In yet another embodiment of the invention, there is provided an emboli capturing device for use in a blood vessel that includes a tube with a plurality of slots therein such that the tube is expandable in the radial direction. The device also includes a membrane surrounding the tube, in which the membrane expands as the tube expands. The membrane has a porosity that is selected to permit the perfusion of blood while capturing emboli travelling through the blood vessel. The tube is adjustable into a retracted position (in which the device has a cross sectional profile that

allows the device to pass through the blood vessel) and a deployed position (in which the device has a cross sectional profile such that the device seals against the blood vessel). Blood that passes from one side of the device to another side of the device passes through porous regions of the membrane. One preferred embodiment further comprises a pull wire that passes through the elongate member and is secured to the tube near a tip of the tube, in which the pull wire deploys the tube from the retracted position to the deployed position when the pull wire is moved longitudinally.

In another aspect of the invention, there is provided a method of forming an emboli-capturing device for use in a blood vessel which comprises providing a hypotube, forming slots in a first portion of the hypotube to form a flexible, elongate portion capable of being navigated through the blood vessel, and forming slots in a second portion of the hypotube to form a portion that is expandable in the radial direction. The method further includes positioning a porous membrane around at least a part of the second portion, in which the porosity of the membrane is selected to allow the perfusion of blood while capturing emboli. The method further includes forming slots in a third portion of the hypotube to form a flexible tip that can be navigated through the blood vessel, wherein the second portion is located in the longitudinal sense between the first portion and the third portion.

In yet another aspect of the invention there is provided a method of filtering emboli from blood in a blood vessel that includes providing a hypotube. The hypotube includes slots in a first portion of the hypotube that form a flexible, elongate portion capable of being navigated through the blood vessel, slots in a second portion of the hypotube that is expandable in the radial direction (with a porous membrane positioned around at least part of the second portion), and slots in a third portion of the hypotube that form a flexible tip (such that the second portion is located between the first portion and the third portion in the longitudinal sense). The method also includes introducing the tip into the blood vessel, and positioning the second portion and the membrane at a selected location within the blood vessel. The second portion is expanded so that a seal is made with the blood vessel, such that emboli within the membrane are captured while blood perfuses through the membrane.

In yet another preferred embodiment of the occlusion device, the hypotube on either side of the expandable filter is cut in a spiral formation, thereby enabling greater flexibility in the longitudinal direction. Preferably, the number of loops of the spiral per distance length will be greater on the distal side of the filter than on the proximal side, to allow greater flexibility of the hypotube distally rather than proximally of the filter. This serves to create a gradual increase in flexibility from the proximal to the distal end of the hypotube.

Brief Description of the Drawings

FIGURE 1 is a partial sectional view of a shaft and filter subassembly deployed in a blood vessel, as well as a friction fit mechanism located proximal of the filter subassembly.

FIGURE 2 is a side view of a strut hypotube of the filter subassembly.

FIGURE 3 is a perspective view of the strut hypotube.

FIGURE 4 is a sectional view of the strut hypotube, taken along the line A-A in **FIGURE 2.**

FIGURE 5 is a side view of a pull wire for use in the shaft and filter subassembly.

FIGURES 6 and **7** are partial cross-sectional views of a kink protection system for the pull wire, reflecting system conditions when the filter subassembly is in the contracted and expanded configurations, respectively.

FIGURES 8A-8C show an adapter for use with the shaft and filter subassembly of **FIGURE 1**.

FIGURE 9 illustrates another embodiment of an adapter for use with the shaft and filter subassembly of **FIGURE 1**.

FIGURE 10 shows a side view of a deployed filter subassembly including the struts and membrane of the filter as they would lie within a blood vessel.

FIGURES 11A and **11B** show partial cut away side views of a laser cut hypotube with a pull wire and an outer retrieval hypotube in an expanded and collapsed configuration, respectively.

FIGURE 12 shows a side view of an integrally formed set of straight struts in the collapsed configuration.

FIGURE 12A shows a cut-away view through line 12A-12A on **FIGURE 12** showing the slits cut into the hypotube.

FIGURE 13 shows the struts of **FIGURE 12** in the expanded configuration.

FIGURE 14 shows a side view of an integrally formed set of spiral struts in the collapsed configuration.

FIGURE 15 shows the spiral struts of **FIGURE 14** in the expanded configuration.

FIGURES 16A and **16B** show partial cut-away views of a buckled set of struts in use in a narrow blood vessel.

FIGURE 17A shows a side view of a hinge formed by flattening a section of a strut.

FIGURE 17B shows a plan view of a hinge formed by flattening a section of a strut.

FIGURE 18A shows a hinged strut subject to a bending force.

FIGURE 18B shows an unhinged strut subject to a bending force.

FIGURE 19 shows a partial cut-away view of a strut structure which uses flattened hinges.

FIGURE 20 shows a side view of an alternate strut structure which uses flattened hinges.

FIGURE 21 shows a cut-away side view of a tension actuated strut system in the expanded configuration.

FIGURE 21A shows a partial cut-away side view of a sheath actuated strut system in the expanded configuration.

FIGURE 21B shows a partial cut-away side view of a sheath actuated strut system in the collapsed configuration.

FIGURES 21C and **21D** show partial cut away side views of an alternate sheath actuated strut system in the collapsed and expanded configurations, respectively.

FIGURE 22A shows a partial cut-away isometric view of a torsion actuated strut system in the collapsed configuration.

FIGURE 22B shows a partial cut-away isometric view of a torsion actuated strut system in the expanded configuration.

FIGURE 23 shows a side view of a single membrane, single strut system, single actuator device in accordance with a preferred embodiment of the present invention.

FIGURE 24 shows a side cross-section view of a double membrane, single strut system, single actuator device in accordance with a preferred embodiment of the present invention.

FIGURE 25 shows a side view of a double membrane, double strut system, single actuator device in accordance with a preferred embodiment of the present invention.

FIGURE 26 shows a side cross-section view of a double membrane, double strut system, double actuator device in accordance with a preferred embodiment of the present invention.

FIGURE 26A shows a partial cut-away isometric view of a three member shaft in accordance with one preferred embodiment of the present invention.

FIGURE 27A is a longitudinal cross sectional view of a perfusion-filter embodiment comprising a radiopaque element secured to an expandable member, in which the expandable member includes a plurality of ribbons and a porous membrane that allows perfusion of blood while containing emboli.

FIGURE 27B is a cross sectional view of the perfusion-filter embodiment of **FIGURE 27A**.

FIGURE 27C illustrates how bending the ribbons of the expandable member results in the vessel contacting the ribbons at the bends.

FIGURE 28A is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a braid, and in which the radiopaque element includes wires extending in the longitudinal direction.

FIGURE 28B is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a braid, and in which the radiopaque element includes wires oriented in the radial direction.

FIGURE 28C is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a filter-like mesh.

FIGURE 29A is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a plurality of coils, and in which the radiopaque element is secured to the coils using a heat-to-shrink material.

FIGURE 29B is a radial cross sectional view of the embodiment of **FIGURE 29A** showing the relationship between the coils, the radiopaque element, and the heat-to-shrink material.

FIGURE 30 is a longitudinal cross sectional view of an expandable member that includes a slotted tube, with a radiopaque element that includes a layer on the slotted tube.

FIGURE 31A illustrates a dipping technique for forming a porous membrane on an expandable member.

FIGURE 31B shows the dried membrane formed on the expandable member.

FIGURE 32 is an embodiment in which an elongate flexible section, an expandable member, and a distal tip are integrally formed from a single hypotube.

FIGURE 33 shows a perfusion-filter device formed from a hypotube, with the perfusion filter being shown in the deployed configuration.

Detailed Description of the Preferred Embodiment

The following description and examples illustrate preferred embodiments of the present invention in detail. Those of skill in the art will recognize that there are numerous variations and modifications of this invention that are encompassed within its scope. Accordingly, the description of preferred embodiments should not be deemed to limit the scope of the present invention.

OVERVIEW OF THE OCCLUSION SYSTEM

FIGURE 1 illustrates a preferred embodiment of a filter device 10 comprising a shaft 12, a filter subassembly 14, and a guide tip 16. An adapter 118 (see **FIGURES 8A-9**) may be operably connected to the filter device to expand the filter. Further details of each of these components are described below.

In employing the device 10, the filter subassembly 14 is delivered on the shaft 12 to a location in a blood vessel 18 distal of an occlusion 20. Through the use of the adapter 118, the filter subassembly 14 is expanded to occlude the vessel distal of the occlusion. Various therapy and other catheters can be delivered and exchanged over the shaft 12 to perform treatment on the occlusion 18. Because the filter subassembly 14 remains expanded distal of the occlusion 18, any particles broken off by treating the occlusion 20 are trapped within the filter subassembly. These particles may then be removed by contracting the filter subassembly 14 so as to contain the particles and withdrawing the device 10 from the vessel. As an alternative or in addition to this method of particle removal, an aspiration catheter may be delivered over the shaft 12 and used to aspirate some or all of the particles from the filter subassembly 14.

Shaft

As shown in **FIGURE 1**, the shaft 12 comprises an outer shaft member 22, and a pull wire 24 which extends through the lumen of the outer shaft member. The outer shaft member 22 may comprise a hypotube as is known in the art. Multiple hypotubes may be coaxially disposed over the pull wire 24. The shaft extends from a proximal end distally to the filter subassembly 14. The shaft may be constructed to any desired length, however, it is preferable for the shaft to be between about 120 and 300 cm in length.

The size of the outer member of the shaft 12 is suitable for insertion into the vasculature of a patient through an insertion site in the skin of the patient. It is preferable that the outer shaft member 22, the pull wire 24, and any other hypotube members are disposed coaxially such that each member is located within any larger diameter member and surrounds any smaller diameter member.

It is preferable that the largest diameter member of the shaft, for example outer member 22 in **FIGURE 1**, has an exterior diameter of about 0.009 to 0.035 inches. It is more preferable that the largest diameter member of the shaft has an exterior diameter of about 0.012 to 0.035 inches, more preferably about 0.014 to 0.018 inches, and most preferably about 0.0142 inches. The wall thickness of the largest diameter hollow member of the shaft is preferably about 0.001 to 0.008 inches; i.e. the diameter of the lumen of the largest hollow member of the shaft is preferably from about 0.002 to 0.016 inches less than the outer diameter of the member. Any members located within the largest diameter member are preferably sized so as to fit within the inner lumen of the larger member.

As shown in **FIGURE 1**, the outer member 22 of the shaft extends distally and is connected at its distal end to the filter subassembly 14. The pull wire 24 is the most centrally disposed of the shaft members. The pull wire 24 is preferably a solid, i.e. non-tubular member around which the outer member 22 is disposed. The pull wire 24 preferably extends inside the outer member 22, through the filter subassembly 14, and into the guide tip 16. Alternatively, the pull wire 24 may have two or more distinct segments, such as a proximal segment which extends to and terminates at the distal end of the strut hypotube 30 and a distal segment which extends from that point to the distal end of the guide tip 16.

In order to have different mechanical properties at different positions along the axial length of the shaft, it may be preferable to use different materials at different positions along the shaft. This can be accomplished by constructing each elongate member of the shaft out of separate cylindrical members which are joined end-to-end. One example of the usefulness of such a technique involves varying the material for the outermost member of the shaft. One material could be used for the most proximal portion of the outermost member, suitable for mechanically interacting with the adapter. A different material could be used for the distal portion of the outermost shaft member, suitable for bending and flexing as the shaft is advanced to the treatment site. Similar advantages can apply to using different materials at different axial positions for the core wire, or any other member of the shaft. Such portions constructed of different materials may be joined together by means such as crimping, adhesive bonding, heat fusing, or soldering.

The shaft members 22, 24 are preferably formed from a material which is sufficiently strong to support the shaft 12 itself as well as the filter subassembly 14 at the distal end under the tension, compression, and torsion experienced when inserting, operating, and removing the device from the vasculature of a patient. The material is preferably also sufficiently flexible and elastic that it does not develop permanent deformation while being threaded through the curved path necessary to reach the treatment site from the insertion point. In a preferred embodiment, the shaft 12 has a friction-reducing outer coating of TEFLON®.

In order to satisfy these requirements, it is preferable to use a metallic tube or wire to form the shaft members 22, 24, although a braided or non-braided polymer tube may also provide the desired characteristics. More preferably, a superelastic memory alloy such as straight-annealed nitinol is used for the outer shaft member 22; tempered stainless steel is one preferred material for the pull wire 24. Other suitable alloys for the shaft members include nitinol-stainless steel alloys, or nitinol alloyed with vanadium, cobalt, chromium, niobium, palladium, or copper in varying amounts.

Filter Subassembly

Still referring to **FIGURE 1**, the filter subassembly 14 extends from the distal end of the shaft 12. The filter subassembly 14 preferably comprises an expandable member which is either integrally formed or separately attached (as shown in **FIGURE 1**) to the distal end of the shaft 12. The expandable member preferably includes an occlusive member or membrane 26 and provides support for this occlusive member.

As used herein, "occlusion" or "sealing", and the like, refer to blockage of fluid flow in a vascular segment, either completely or partially. In some cases, a complete blockage of the blood vessel may not be achievable or even desirable, for instance, when blood flow must be maintained continuously to the region downstream of the occlusive device. In these cases, perfusive flow through the occluded region is desirable and a partial blockage is used. For example, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does not span the entire blood vessel. Alternatively, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does substantially span the entire blood vessel, but which contains openings or other means for flow to move through the occlusive member perfusively. In other cases, a partial blockage may not be achievable or desirable, and an occlusive member which substantially spans the cross section of the blood vessel without allowing perfusion is used. Each of these described structures makes use of "occlusion," as defined herein.

In the embodiment shown in **FIGURE 1**, the expandable member comprises struts 28 which are formed in a strut hypotube 30. The strut hypotube 30 extends from the distal end of the outer shaft member 22 to the proximal end of the guide tip 16. At its proximal end the strut hypotube 30 is soldered, crimped, and/or bonded, or otherwise affixed to the distal end of the outer shaft member 22. In a preferred embodiment, a proximal taper 31a, preferably formed from a flexible UV-cured adhesive, facilitates the connection of the strut hypotube 30 to the shaft 12. At its distal end the strut hypotube 30 is crimped over a solder junction between the pull wire 24 and the proximal end of the guide tip 16. A distal taper 31b, also preferably formed from a flexible UV-cured adhesive, may be employed as well in attaching the strut hypotube 30 to the guide tip 16. With the strut hypotube, pull wire and guide tip joined in this manner, a proximal movement of the pull wire with respect to the outer shaft member 22 causes a corresponding proximal movement of the distal end of the strut hypotube, thus compressing the strut hypotube and urging the struts toward the expanded position.

The strut hypotube 30 is preferably formed from nitinol, but may alternatively be formed from nitinol-stainless steel alloys, or nitinol alloyed with vanadium, cobalt, chromium, niobium, palladium, or copper in varying amounts. The strut hypotube preferably has an outside diameter of about 0.021 inches and an inside diameter of about 0.014 inches.

As best seen in **FIGURES 2** and **3**, the individual struts 28 are preferably cut from, and thus integral to, the strut hypotube 30. The struts 28 may advantageously be formed by subjecting the strut hypotube 30 to a laser-cutting process. Although the number of struts 28 may vary, there are preferably between 4 and 10 (most preferably 8) struts. The struts 28 should be equally radially spaced about the longitudinal centerline of the strut hypotube 30.

It is preferred that the struts 28 have a helical configuration, with each strut making approximately 1.0 revolution, at a substantially constant pitch, about the longitudinal centerline of the strut hypotube 30 as it extends from its proximal to its distal end. Alternative preferred embodiments have straight slits which provide for non-spiral struts when deployed into the expanded configuration. The preferred helical configuration improves the apposition of the struts against the vessel wall when the filter subassembly is in the expanded configuration. The struts 28 may advantageously have a constant clockwise pitch of about 0.650 inches and therefore the portion of the hypotube into

which the struts are cut is about 0.650 inches in length. It is contemplated that the filter subassembly should reach a preferred maximum diameter of about 7.5 mm when expanded. As used herein, "strut" refers to any mechanical structure which extends from another structure or which is used to support a membrane or other structure of the occlusion device. Specifically, as discussed herein, the struts of the occlusion device are those portions of the device which extend from the shaft in order to adjust the profile of the device as discussed below, and which may be used to support the membrane.

FIGURE 4 depicts a cross-section of the strut hypotube 30, taken along the line 4-4 as shown in **FIGURE 2**. The preferred laser-cutting process creates a gap of about 0.0018 inches in width between each pair of struts 28. Each strut 28 thus has a preferred cross-section that comprises an angular section of an annulus, with a smaller-radius inner surface 28a and a broader, larger-radius outer surface 28b. By virtue of their increase in size near the outer surface 28b, the struts 28 are stronger than a comparable set of struts that have a simple rectangular cross-section and are sized to fit within the same inner diameter-outer diameter "envelope."

With further reference to **FIGURES 2** and **3**, the strut hypotube 30 may preferably incorporate a proximal cut 32 and/or a distal cut 34, to improve the flexibility of the hypotube. Each of the cuts 32, 34 is helical, with the proximal cut 32 having a preferred substantially constant pitch of about 0.030 inches and the distal cut 34 having a preferred substantially constant pitch of about 0.020 inches. The proximal cut 32 and distal cut 34 preferably extend along about 0.075 inches and 0.125 inches, respectively, of the hypotube 30 (as measured along its longitudinal axis), and each has a preferred cut width of about 0.0018 inches. Preferably, an uncut "gap" of about 0.015 inches exists on the strut hypotube 30 between the proximal cut 32 and the proximal end of the struts 28, and between the distal cut 34 and the distal end of the struts. As shown in **FIGURE 1**, when the strut hypotube 30 is attached to the shaft 12 and the guide tip 16, it is advantageous that no part of the cuts 32, 34 overlie any portion of the shaft or guide tip, so as not to impede the flexibility enhancement that is provided to the strut hypotube by the cuts.

In a preferred embodiment, one or more marker bands 36 (see **FIGURE 1**) are attached to a corresponding number of the struts, and are advantageously located at or near the midpoint of each strut, so as to align the marker bands with the widest portion of the filter subassembly 14 when it is in the expanded configuration. The marker bands may thus be aligned in a plane extending substantially orthogonal to the longitudinal axis of the shaft 12. Alternatively, the marker bands 36 may be staggered, i.e. attached in varying locations along the length of the struts 28, in order to reduce the profile of the filter subassembly when it is in the collapsed configuration. The marker bands are advantageously configured to wrap around only three sides of each strut, leaving the outer surface 28b (see **FIGURE 4**) exposed, in order to reduce the profile of the filter subassembly when it is in the expanded configuration. A proximal marker band (not shown) may be incorporated in a location proximal of the struts 28 to mark a point on the device beyond which a catheter positioned on the shaft 12 should not be advanced, thus preventing inadvertent collapse of, or damage to, the struts 28. A preferred location for the proximal marker band is at the junction of the shaft 12 and the strut hypotube 30, underlying the proximal taper 31a.

The marker bands 36 are formed from a material having increased radiopacity in comparison to the rest of the filter subassembly, such as platinum, gold, or alloys thereof. In a preferred embodiment, the marker bands comprise an alloy of 80% platinum and 20% iridium.

As shown in **FIGURE 1**, the pull wire 24 extends past the distal end of the outer shaft member 22, beyond the strut hypotube 30, and terminates in a solder joint 35 at the distal end of the distal tip 16. The tip 16 distal to the struts 28 preferably includes a radiopaque coil material, most preferably platinum, extending between the distal end of the strut hypotube and the solder joint 35 to aid the practitioner in positioning the expandable member 14 within the vessel 18.

The membrane 26 is preferably attached at its proximal end to the struts 28, at or proximal of the struts' widest extent when in the expanded configuration. It is also preferred that the membrane 26 is attached at its distal end to the strut hypotube at or adjacent the distal cut 34. Between these proximal and distal points of attachment, the membrane tapers gradually to a smaller diameter but preferably tapers less sharply than the distal portion of the struts 28, so as to remain free from the struts, in a relatively loose or "baggy" state. When the expandable member is deployed, this "baggy" membrane creates a rather deep pocket for catching emboli as blood flows through the membrane 26, and for containing the emboli when the expandable member is collapsed and withdrawn from the vessel 18.

Alternatively, the membrane 26 may be attached to the struts 28 at one or more points, or in a continuous attachment, between the proximal and distal ends of the membrane. Many other arrangements are possible for the structure and attachment of the membrane 26 As used herein, "filter" and like terms mean any system which is capable of separating something out of a portion of the blood flow within the vascular segment, whether or not there is perfusion through the "filter". "Filtering" and similar terms refer to the act of separating anything out of a portion of the blood flow.

The membrane 26 has a number of pores (not shown) of a suitable size to trap emboli while permitting blood to flow through, and are thus about 20-100 microns in size. Suitable nonelastomeric materials for the membrane 26 include polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. The membrane may also be made from latex or silicone. The membrane may alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

Most preferably, the membrane 26 is formed from polyurethane and has pores of about 100 microns in size, or a combination of pore sizes within the ranges detailed above. The pores are preferably spaced apart on the membrane with about 0.006 to 0.012 inches between the centers of adjacent pores, more preferably about 0.010

inches. It is also preferred that the proximal portion of the membrane lack pores, to facilitate bonding the membrane to the struts 28 over the marker bands 36. Likewise, the distal portion of the membrane may also be nonporous, providing easier attachment to the strut hypotube 30.

Pull Wire

The outer shaft member 22 surrounds the pull wire 24 and is connected to the strut hypotube 30 at its proximal end (see **FIGURE 1**). The pull wire 24 is advantageously attached to distal end of the strut hypotube 30, so that when the pull wire 24 is retracted relative to the outer shaft member 22, the struts 28 are urged to expand in a radial direction. The relative position of the outer shaft member 22 and the pull wire 24 is varied until the vessel 18 is occluded. The struts 28 bow outwards toward the wall of the vessel 18, so that the filter subassembly 14 seals the vessel 18 (i.e., in its deployed position, the expandable member prevents emboli from moving downstream). The radial expansion of the struts 28 may also be facilitated by advantageously imparting an initial curvature to the struts 28 through heat setting. The pull wire 24 may advantageously extend within the distal guide tip 16 beyond the distal end of the strut hypotube 30 and terminate in the solder joint 35 at the distal end of the guide tip.

After the filter subassembly 14 is deployed, the struts 28 tend towards their collapsed, undeployed position in the absence of a restraining force (unless the filter subassembly 14 is self-expanding, in which case the filter subassembly has a tendency to remain in the deployed position). To prevent the struts from returning to their undeployed position, the pull wire 24 has one or more bends 38 formed therein for contacting the inner wall of the outer shaft member 22, thereby providing frictional forces which keep the filter subassembly 14 in its expanded, deployed position, as shown in **FIGURE 1**. Specifically, the frictional force between the pull wire 24 and the outer shaft member 22 is sufficient to offset or compensate for the spring force provided by the struts 28 and/or the membrane 26, which would otherwise urge the struts towards their relaxed position. About 0.5-1 pound of pulling force may be required to expand the struts 28. Thus, the bends 38 of the pull wire 24 engage the outer shaft member 22 to form a compact device for restraining the pull wire from unwanted longitudinal motion. The bends 38 of the pull wire 24 may be formed, for example, by coining or by forming a spring in the pull wire. The bends 38 thus act as a locking member which inhibits movement of the pull wire 24, and the pull wire 24 and the outer shaft member 22 are frictionally secured together.

The pull wire features of the embodiment of **FIGURE 1** can also be used if the filter subassembly 14 is shape set so that it tends toward an expanded, deployed position in the absence of any applied forces, i.e. if the expandable member is self-deploying. In the case where an embodiment such as that shown in **FIGURE 1** is constructed using a self-deploying filter subassembly 14, the pull wire 24 effectively acts as a push-wire which holds the filter subassembly in the collapsed configuration. This push-wire is held in place by the frictional engagement between the bends 38 of the pull wire and the outer shaft member 22.

When using such a device as shown in **FIGURE 1** with an expandable member which is self-deploying, the filter subassembly 14 is inserted into the vessel 18 of the patient in its low profile position, with frictional forces between the pull wire 24 and the outer shaft member 22 holding the pull wire 24 in the distal direction, which prevents

the filter subassembly from expanding. The filter subassembly 14 is then deployed by urging the pull wire 24 in the proximal, axial direction (retracting the pull wire) with sufficient force to overcome the frictional forces between the pull wire 24 and the outer shaft member 22, thereby moving the locking member 38 out of its locked position. In effect, by moving the pull wire proximally in this way, the "pushing" effect of the pull wire is eliminated, and the expandable member will deploy into the expanded configuration.

FIGURE 5 shows one preferred embodiment of the pull wire 24. A preferred pull wire 24 comprises a tempered stainless-steel wire with an anti-friction coating of TEFLON®. This pull wire 24 has a tapered configuration, with a proximal section 40 having a diameter of about 0.0086 inches; advantageously, this larger-diameter proximal section of the pull wire includes the bends 38 described above. Distal of this section the pull wire tapers to a medial section 42 having a diameter of about 0.007 inches. The pull wire shown has a diameter of about 0.0025 inches at its most distal section 44; this diameter advantageously prevails over the most distal 3 cm of the pull wire. A tapered transition 46 of about 3 cm in length is interposed between the medial section and the distal section. The pull wire of **FIGURE 5** has an overall length of about 212.0 cm; the proximal section (having the diameter of about 0.0086 inches) is about 17.0 cm in length. The medial section is thus about 189.0 cm in length.

Pull Wire Kink Protection

FIGURES 6 and **7** depict a kink protection system 100 that may preferably be used to prevent the proximal portion of the pull wire 24 from kinking when it is pushed distally against the frictional resistance of the bends 38 and, where the filter subassembly 14 is of the self-expanding type, against the spring force of the struts 28. The system 100 comprises a pre-expanded coil 102 and a proximal hypotube 104. The coil 102 is connected to the proximal tip of the outer shaft member 22 by soldering or other conventional methods and surrounds that portion of the pull wire 24 which is immediately proximal of the outer shaft member. The proximal hypotube 104 is crimped to the pull wire 24 and is attached to the proximal end of the coil 102 by soldering or other conventional methods.

FIGURE 6 shows the system 100 when the filter subassembly is in its contracted configuration, and the coil 102 is compressed. **FIGURE 7** shows the system 100 when the filter subassembly is in the expanded configuration. The pull wire 24 has been pulled proximally from the outer shaft member 22 and the coil 102 is in its relaxed state. When the pull wire 24 is pushed back distally into the outer shaft member 22 (see **FIGURE 6**), the coil 102 augments the column strength of the pull wire 24 by presenting a coaxial, larger-diameter column for absorbing the compressive force that is applied to the coil-pull wire assembly. Off-axis loads are thus less likely to bend or kink the pull wire 24 as it is pushed into the outer shaft member 22.

Adapter

The pull wire 24, shown in **FIGURE 1**, is manipulated through the use of an adapter or manifold 118 (see **FIGURES 8A-9**). The adapter enables the technician to control the relative positioning of the pull wire 24 and the outer shaft member 22 in a simple manner. Although **FIGURES 8A-9** illustrate the adapter as manipulating the pull wire 24, it will be appreciated that in embodiments wherein a proximal hypotube is provided over the pull wire 24, the adapter manipulates this proximal hypotube.

After delivery of the device to the desired location within the vasculature of the patient, the adapter 118 is attached and the pull wire 24 is manipulated through the use of the adapter 118 so as to deploy the filter subassembly 14 of the device. At this point, the adapter may be removed from the device so that therapy may be performed.

One type of adapter 118 used in accordance with preferred embodiments of the filter device is shown in **FIGURES 8A-8C**. Without regard to whether the expandable member is of the shape set variety (self-expanding) or is undeployed when relaxed, the degree to which the expandable member is deployed can be monitored by noting the longitudinal position of the pull wire 24. This allows the user to carefully control the extent to which the expandable member is deployed. A thumb wheel 134 is used to control the position of the pull wire 24 relative to the outer shaft member 22, thereby controlling the extent to which the filter subassembly 14 of **FIGURE 1** is expanded. As illustrated by the view of **FIGURES 8B-8C**, the adapter 118 includes two halves 136, 138 preferably formed of medical grade polycarbonate or the like.

The two halves 136, 138 are attached by at least one hinge 140, so that the halves are joined in a clam shell manner. A latch 142 secures the two halves 136, 138 while the adapter 118 is in use. The latch includes a pair of flexible, resilient latching members 144, 146 which are mounted within the half 138. A space 148 between the two latching members 144, 146 receives a locking pin 150 which has a beveled head 152. The head 152 passes through the space 168 and past the latching members 144, 146. The latching members 144, 146 prevent the locking pin 180 from backing out past the latching members which would open up the adapter 118. To open the halves 136, 138, the latching members 144, 146 are separated slightly by depressing a flexure member 154, which pries apart the latching members slightly, thereby freeing the locking pin 150.

The outer shaft member 22 may be held in place by a groove (not shown) having a width selected to accept the outer shaft member 22. Alternatively, as shown in **FIGURE 8C**, the outer shaft member 22 and the pull wire 24 may be held by clips 156a, 156b, 156c, 156d having respective slots 158a, 158b, 158c, 158d therein for receiving the outer shaft member and the pull wire. In particular, the outer shaft member 22 and the pull wire 24 may advantageously be configured so that the outer shaft member rests within clips 156a, 156b, 156c, with the pull wire extending between the clip 156c and the clip 156d and extending proximal to the clip 156d. With this arrangement, and when the adapter 118 is in the closed position, the pull wire 24 may be engaged and moved by a first pair of contact members such as oppositely facing pads 160a, 160b, while the outer shaft member 22 is held stationary by one or more other pairs of oppositely facing pads 160c, 160d and 160e, 160f. Alternatively, the device may be designed so that the outer shaft member 22 is moved while the pull wire 24 remains stationary. The pads 160a-f may advantageously include a plurality of ridges 162 for securely contacting the pull wire 24. The clips 156a, 156b, 156c, 156d fit within respective cavities 164a, 164b, 164c, 164d in the adapter half 136 when the two halves 136, 138 are closed.

To aid the user in properly aligning the outer shaft member 22 and the pull wire 24 within the adapter 118, a mark may be placed on the outer shaft member 22. For example, an alignment mark on the outer shaft member 22 may indicate that point on the outer shaft member 22 which must be placed within the slot 158a so that the outer

shaft member extends within the adapter 118 up to but not proximally beyond the clip 156c, with the pull wire 24 being exposed proximal to the clip 156c. This configuration permits the pads 160a, 160b to retract (or advance) the pull wire 24 into (or out of) the vessel while the outer shaft member 22 is held securely within the pads 160c, 160d and 160e, 160f.

When the pull wire 24 is not being advanced or retracted through the outer shaft member 22 by the pads 160a, 160b, relative movement of the pull wire and the outer shaft member is advantageously prevented by frictional contact between the bends 38 of the pull wire 24 and an inner surface of the outer shaft member 22 (see **FIGURE 1**). This permits the introduction of a therapy catheter (not shown) such as an angioplasty or stent catheter, or the exchange of a plurality of catheters, after the adapter 118 is decoupled and removed from the outer shaft member 22 and the pull wire 24. For example, once the filter subassembly 14 is deployed, an angioplasty or stent catheter may be introduced over the outer shaft member 22 and the pull wire 24. After therapy is performed, an aspiration (and/or irrigation catheter) may be introduced over the outer shaft member 22/pull wire 24 to aspirate (and/or irrigate) away emboli entrained in the filter subassembly 14 which were produced as a result of the therapy procedure. The adapter 118 may then be recoupled to the outer shaft member 22 and the pull wire 24, followed by deactivation (retraction) of the filter subassembly. The filter subassembly 14, the pull wire 24, and the outer shaft member 22 may then be removed from the vessel.

When the adapter 118 is in the closed position, the pads 160c, 160d, 160e, 160f surround and contact the outer shaft member 22 to prevent its motion. The pads 160a, 160b, on the other hand, are mounted in respective holders 161a, 161b which are slidable within respective recessed portions 163a, 163b of the adapter 118, so that when the pads 160a, 160b, surround and contact the pull wire 24, the pull wire may be retracted or advanced. Specifically, the holder 161a (housing the pad 160a) is mechanically coupled to and controlled by the wheel 134, as discussed in more detail below. When the adapter 118 is closed, the pads 160a and 160b are compressed together and squeeze the pull wire 24 between them. As the user rotates the wheel 134, the pad 160a is moved in the longitudinal direction, and the pad 160b and the pull wire 24 are moved along with it. Thus, by rotating the wheel 134, the user may control the longitudinal position of the pull wire 24 with respect to the outer shaft member 22, and thereby control the extent to which the expandable member is radially deployed. The pads 160a-f may be formed from C-Flex or Pebax and are preferably about 0.5-1.0" long, 0.25-0.5" wide, and 0.125-0.25" thick.

The wheel 134 imparts motion via a cam mechanism (not shown) to the pad 160a which moves the pull wire 24 incrementally. The wheel 134 may advantageously move the pull wire 24, for example, between 3 mm and 20 mm as indicated by a dial 135 on the face of the wheel (see **FIGURE 8A**), thereby controlling the extent to which the expandable member is expanded by controlling the position of the pull wire. The dial 135 acts as a gauge of the relative longitudinal position of the pull wire 24 within the vessel, and thus as a gauge of the extent to which the expandable member has been expanded.

Another embodiment of the adapter 118 is shown in **FIGURE 9**. This embodiment has the same basic configuration as that shown in **FIGURES 8A-8C**, i.e., a clamshell with two halves 136, 138 rotatably connected by at

least one hinge 140. A resilient locking clip (not shown) may be mounted in a recess 180 formed in the upper half 136 and extend downward therefrom. Upon closure of the adapter 118 an inwardly-extending tongue formed on the locking clip snaps into a groove 182 formed in the lower half 138. The locking clip holds the adapter 118 firmly closed by virtue of an interference fit between the tongue and the groove 182.

In place of the thumb wheel 134 shown in **FIGURES 8A-8C**, this embodiment of the adapter 118 incorporates a knob 184 that is rotated by the user to move the pads 160a, 160b and advance/retract the pull wire 24. Like the thumb wheel 134, the knob 184 may incorporate appropriate markings (not shown) to indicate the extent to which the filter has been expanded or retracted by the action of the adapter 118.

Like the adapter shown in **FIGURES 8A-8C**, the adapter 118 of **FIGURE 9** includes pads 160c, 160d, 160e, 160f that grip the outer shaft member and hold it stationary while the pull wire is advanced or retracted within it. Clips 156a, 156b, 156c having respective slots 158a, 158b, 158c receive the outer shaft member and/or pull wire and maintain it in a straight configuration for the filter deployment/retraction process. Upper and lower channel halves 186a, 186b coact to create, upon closure of the adapter 118, a channel that receives and grips the outer shaft member and the pull wire, preferably immediately adjacent the pads 160a, 160b.

A pin member 188 is positioned on the upper half 136 so that the pin 188 is depressed by the pull wire when the adapter 118 is closed with the outer shaft member and pull wire positioned therein. The pin member is mechanically coupled to an interrupt mechanism (not shown) that prevents rotation of the knob 182 unless the adapter 118 is closed with the pull wire, etc. in position (and the pin member 188 depressed by contact with the pull wire).

Strut Design

With further reference to **FIGURE 1**, the filter device includes a filter subassembly 14 which is located along the shaft 12 near the distal end, and proximal of the guide tip 16. In one embodiment the filter subassembly may be integrally formed with the outer member 22 of the shaft 12. The filter subassembly 14 comprises a number of struts 28 and an occlusive member or membrane 26. The struts support the membrane, and provide for at least two configurations of the device, a collapsed configuration and an expanded configuration. The expanded configuration is shown.

The "collapsed" configuration refers to the lowest profile configuration of the struts. In this context, "profile" refers to the distance away from the axis of the device that is spanned. Therefore, "low profile" refers to configurations in which the device is entirely within a small distance from the axis of the device. The "collapsed configuration" is the configuration in which the struts have the lowest possible profile, that is, where they lie as close as possible to the axis of the device. Having a low profile configuration simplifies insertion and removal of the device, and strut designs which tend to reduce the profile of the occlusion device are advantageous.

In the collapsed configuration, the embodiment shown in **FIGURE 1** would have the struts 28 and the occlusive member 26 positioned as close as possible to the longitudinal axis of the device, i.e. they would have the smallest possible cross-section. This configuration facilitates the deployment of the filter subassembly 14 by permitting easier delivery through the blood vessel 18 on the distal end of a catheter shaft, as well as easier retrieval

of the filter subassembly 14 at the conclusion of the procedure. By minimizing the profile of the filter subassembly, this configuration is more easily passed through the vasculature leading to the filtration site from the insertion point.

When moved from the expanded configuration, shown in **FIGURE 1**, into the collapsed configuration, the membrane 26 may not lie in the same profile as it did prior to deployment into the expanded configuration. This is because the membrane is retracted strictly by the action of the struts, and excess folds of material may extend from between the struts in the collapsed configuration. This may cause the profile of the filter subassembly 14 to be larger after retraction than it was prior to deployment. This enlarged profile can cause the membrane 26 to rub against the vessel walls in an undesirable manner. One way to address this difficulty is to use a retrieval catheter as shown in **FIGURES 11A** and **11B**.

In the "expanded" configuration shown in **FIGURE 1**, the struts 28 and the occlusive member 26 are positioned such that they span substantially the entire width of the blood vessel 18 in which they are positioned. This is preferably the highest profile possible for the struts within the blood vessel. This configuration facilitates the use of the filter subassembly 14 to trap embolic matter while permitting passage of blood through the filter subassembly. By providing a means to span substantially the entire width of the blood vessel 18 to be filtered, the struts 28 support the occlusive member 26 in a configuration which forces the blood flow through the vessel to pass through the pores or openings in the filter subassembly 14 while retaining emboli therein. This produces the desired filtering effect.

In one embodiment, the struts are preferably formed by laser cutting slits in a hypotube. Some preferred materials for the hypotube include nitinol, nitinol/steel alloys, and stainless steel. Generally, the same materials as described above for use in the shaft are also preferred for use in the struts. For example, in one preferred embodiment, a nitinol hypotube with a diameter of .018" is used. The hypotube is laser cut in a spiral configuration to provide for struts which take a spiral shape when adjusted into the expanded configuration, as described below. Alternative preferred embodiments have straight slits which provide for non-spiral struts when deployed into the expanded configuration.

Actuation of the struts in order to adjust the device from the collapsed configuration to the expanded configuration (shown in **FIGURE 1**) is achieved using either a tension or a torsion mechanism. In tension based actuation, the pull wire 24 is displaced axially within the outer shaft member 22 in a proximal direction. In one preferred embodiment, this displacement allows the struts to expand under a built-in bias into the expanded configuration. In the embodiment shown in **FIGURE 1**, the displacement applies an outward biasing force to the struts. In torsion based actuation, the pull wire 24 is rotated with respect to the outer shaft member 22, resulting in a rotational displacement which applies an outward biasing force to the struts. In order to adjust from the expanded to the collapsed configuration, the actuation is reversed, by either pushing or rotating the pull wire in the direction opposite from that used in the deployment, reversing the force upon the struts, and returning the device to the original configuration.

Membrane

As seen in **FIGURE 1**, the occlusive member or membrane 26 is preferably attached to each of the struts 28 and extends completely around the longitudinal axis of the device. Preferably, the occlusive member 26 is attached to the outer surface of the struts 28; however, it may be attached along the inside of the struts 28 as well. Moreover, it will be appreciated that the filter membrane may be provided inside some of the struts and outside of others. It will also be appreciated that struts may be provided on both sides of the membrane in a sandwiched configuration, or that two membranes may sandwich a set of struts.

At its distal end the occlusive member 26 is preferably joined to the strut hypotube 30, or, alternatively, to the guide tip 16. As the occlusive member 26 can be constructed in varying lengths, its proximal end may be located between the midpoint and the proximal end of the struts 28. Where the occlusive member 26 extends along the entire length of the struts 28 it may also be attached at its proximal end to the strut hypotube 30. Thus, when the struts 28 are radially expanded, the occlusive member 26 will likewise expand so as to take on a cross-sectional area corresponding approximately to that of the internal dimensions of the blood vessel 18. It is contemplated that the occlusive member can be joined to the struts 28 and strut hypotube 30 by employing standard attachment methods, such as heat fusing, adhesive bonding, etc.

One preferred occlusive member 26 is a nonelastomeric membrane with a number of pores which are approximately 20-100 microns in diameter. Suitable nonelastomeric materials include, but are not limited to: polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. This type of occlusive member may be extruded or dip molded, with the pores formed by the mold itself, or subsequently using an excimer laser or other drilling process.

One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. The membrane may also be made from latex or silicone. The occlusive member may alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

A variety of pore configurations are suitable for use with the occlusive member. First, where the membrane extends along the entire length of the struts, about 2-10 pores of about 20-200 microns diameter may be arranged longitudinally along the occlusive member to provide perfusion. Another suitable configuration for this type of occlusive member consists of several pores of about 20-200 microns in diameter on the distal half of the member, and large triangular, round, or square cutouts on the proximal half. Alternatively, the entire surface of the occlusive member may have pores of about 20-200 micron size. This configuration is also contemplated for use where the occlusive member 26 has an open proximal end. When using this type of occlusive member, a non-permeable cover or

web may be placed over the juncture of the proximal ends of the struts to the distal shaft, to prevent formation of thrombi in the narrow passages formed at this point.

The membrane may be mounted on the device so as to create a loose or "baggy" portion of the membrane between proximal and distal points of attachment to the struts and to the strut hypotube/guide tip, respectively. In other words, the membrane may have a proximal point or region of attachment to the struts, a baggy portion distal of the proximal point of attachment in which the membrane is unattached to the device, and a distal point of attachment distal of the baggy portion. On such a membrane, the distal and proximal portions that are intended for attachment to the struts, guide tip and/or strut hypotube may preferably be substantially nonporous, to permit better adhesion. In one preferred embodiment, this membrane may have about 400 to 1000 pores, more preferably about 700-800 pores.

The membrane or occlusive member may also comprise a strut-deployable balloon that incorporates perfusion tubes which permit fluid communication (but not flow of emboli) between the proximal and distal sides of the balloon. The perfusion tubes may comprise lengths of tubing which terminate (at their proximal and distal ends, respectively) at points of intersection with the proximal and distal faces of the balloon. Alternatively, perfusion may be facilitated through the lumen of the outer shaft member via openings formed therein proximal of the balloon, and via the (porous) guide tip distal of the balloon. A valve system may be employed to regulate the flow of fluid through the lumen.

The device may also employ dual occlusive members on a single set of struts, with a proximal filter with relatively large pores and a distal filter with smaller pores. With any of the mentioned types of occlusive member, it is contemplated that an aspiration catheter may be employed to remove thrombi from the filter(s) at various points in an angioplasty or other similar procedure.

Guide Tip

As shown in **FIGURE 1**, located most distally upon the shaft 12 is a guide tip 16. The guide tip lies distal of the filter subassembly 14 and provides a flexible leading extension which bends to follow the curvature of the blood vessels through which the device is advanced. By bending to follow the wall of the blood vessel, the guide tip 16 leads the filter subassembly 14 and other more proximal elements of the device in the direction of the tip so as to make the device move through the vessel without excessive impact against the walls of the blood vessels of the patient.

With further reference to **FIGURE 1**, in one embodiment the guide tip 16 is formed by creating a rounded solder joint tip 35 to the pull wire 24 of the shaft 12, and wrapping it in a thinner wire to produce a coil which provides a spring force between the filter subassembly 14 and the rounded tip 35. The wire used for the coil 16 is preferably made of a radiopaque material. Because the pull wire 24 is constructed of a flexible material, such as nitinol, it will bend when the rounded tip 35 is pushed against the curving wall of a blood vessel. However, as the deflection of the tip increases, the spring force of the coil of thinner wire will urge the filter subassembly 14 and shaft 12 into alignment with the guide tip 16. In this way, the entire shaft is made to follow the path of the guide tip 16 as it advances through the blood vessels toward the treatment site.

Operation

The use of the described embodiments of the instant invention will generally be part of a process of therapy on a portion of the blood vessel of a patient. Usually, the therapy will involve treatment of some form of blockage of the blood vessel. However, those skilled in the art will recognize that the use of the described invention is appropriate in any situation where there is a possibility of embolic matter being dislodged from the vasculature of the patient, and therefore a desire to inhibit the dispersal of such embolic matter into the bloodstream of the patient.

As used herein, "method" refers to a preferred sequence used to accomplish a goal. Furthermore, the method which is described below is not limited to the exact sequence described. Other sequences of events or simultaneous performance of the described steps may be used when practicing the instant invention.

First, the device is manipulated so that the filter subassembly or subassemblies are in the collapsed position. This simplifies the insertion of the device into the blood stream of the patient. The device is then inserted through an insertion site into a blood vessel of the patient. Once inserted into the vasculature of the patient, the device is advanced distally until the distal portion of the device is located adjacent to the region of the blood vessel to be treated.

The device is positioned such that the filter subassembly lies generally downstream of the treatment site, or more generally, such that the filter subassembly lies between the treatment site and any site which is of particular susceptibility to embolic damage (e.g., the brain or coronary arteries). In this way, the filter is positioned so as to intercept any embolic matter dislodged at the treatment site, before such embolic material can reach any vulnerable area or be dispersed through the blood flow of the patient.

Once in position, the filter subassembly is actuated so that it assumes its expanded configuration, effectively occluding the blood vessel so that all blood flow must pass through at least one of the filter membranes or other occlusive members of the device.

The desired therapy is now performed upon the region of the blood vessel to be treated. This may involve placement or removal of support stents, balloon angioplasty, or any other vascular therapy that is conducted through the use of interventional techniques. In the course of such interventional treatment, additional catheters or other devices may be introduced to the treatment area by threading them over or along the shaft of the occlusive device. During the therapy, any embolic matter which is dislodged will flow into the filter and be caught by the membranes supported by the struts.

At any point during the therapy, the embolic matter may be aspirated from the filters through the use of separate aspiration catheters or through the lumen of the outer hypotubes forming the shaft of the occlusive device. Such aspiration may be repeated as often as necessary to maintain perfusive blood flow through the filter subassembly and treated region.

When the therapy is concluded, the filter subassembly is retracted into its collapsed configuration by reversing the actuation process. This will return the struts to a low profile which can then be withdrawn from the patient through the insertion site.

ADDITIONAL STRUT DESIGNS

It will also be appreciated that the occlusion device described above may also take other forms as described below.

Another preferred embodiment of a filter assembly in accordance with the current invention is shown in **FIGURE 10**. The filter subassembly 1072 is located along the shaft 1070 near the distal end, and proximal of the guide tip 1076. The filter subassembly is preferably integrally formed with the outer member 1088 of the shaft 1070. The filter subassembly 1072 comprises a number of struts 1082 and an occlusive membrane 1074, such as described above. The struts support the occlusive membrane, as well as providing for at least two configurations of the device, a collapsed configuration and an expanded configuration. The expanded configuration is shown. As shown in **FIGURE 10**, located most distally upon the shaft 1070 is a guide tip 1076 as described above.

FIGURES 11A and **11B** illustrate one embodiment in which struts 1008 are laser cut into a middle hypotube 1020. The distal end of the struts 1008 is preferably crimped onto a core wire or pull wire 1028, which is tapered toward its distal end. To actuate or deploy the filter subassembly, the core wire is pulled in relation to the middle hypotube 1020 to expand the struts 1008 with membrane 1012. To retract the filter, the core wire is pushed distally, and the middle hypotube is pulled such that the struts collapse down into the optional retrieval hypotube 1029. By retracting the filter subassembly through the retrieval hypotube 1029, the blood vessel is protected from damage while the device is removed from the body. This is especially advantageous because the filter membrane 1012 often has a larger profile after particles are trapped therein. This larger profile filter may scrape against the walls of the vessel if extracted without a retrieval hypotube.

It will be appreciated that the retrieval hypotube 1029 is optional in the above embodiment. It will also be appreciated that the retrieval hypotube may take the form of an aspiration catheter which is used prior to removal of the device to aspirate particles trapped within the membrane. Thus, in one embodiment, the filter subassembly is removed through the lumen of the aspiration catheter.

As discussed above and shown in **FIGURE 10**, struts 1082 are used to support the filter membrane 1074 in an expanded configuration so as to span the entire width of the blood vessel 1086 under treatment. In order to provide such support, the struts 1082 need to span the space from the axis of the supporting shaft 1070, described above, to the walls of the blood vessel 1086.

Different means are possible to construct struts appropriate for supporting the filter membrane in accordance with preferred embodiments of the instant invention. These include integral struts formed by cutting slits in a hypotube, or ribbon struts attached to the other shaft components. In all strut designs, it may be preferable to provide a heparin coating upon the surfaces which move or flex. This is especially important on the proximal region of the filter subassembly 1072, shown in **FIGURE 10**, where the struts 1082 meet the shaft 1070. It is in this area that thrombi or other coagulation are most likely to form.

The use of heparin, or another antithrombogenic treatment, is especially desirable for these surfaces because of the dangers posed by formation of embolic matter along these surfaces. One concern is that the presence of

thrombi or other coagulation may impede the functioning of the device if it prevents the flexible parts of the device from bending properly. Even more dangerous is the possibility that the thrombi that form along such flexible surfaces will be dislodged by the motion of such surfaces and not caught by the filter subassembly.

Thrombi which form along the surface of the device are not dangerous as long as they remain attached to the device until it is completely removed from the vasculature of the patient. However, any thrombi which form along a portion of the device which flexes, such as the struts 1082 (see **FIGURE 10**), may be dislodged by the motion of the struts themselves as they retract the filter subassembly 1072 from the expanded to the collapsed configuration. Because the filter subassembly no longer spans the blood vessel once in the collapsed configuration, any thrombus which is dislodged during the retraction of the struts will not be caught in the filter 1074 and will tend to escape downstream into the no longer occluded blood vessel 1086.

Integral Straight Struts

As shown in **FIGURE 12**, one preferred method of constructing filter struts is to cut slits 1155 into the distal portion of a hypotube 1150 shaft member. By cutting slits which are generally parallel to the axis of the hypotube around the entire circumference of the tube, the hypotube 1150 can be now be compressed axially, which will cause the material of the tube to bow outward radially along the length of the cuts and form struts 1160, as shown in **FIGURE 13**. The required compression can be accomplished using a pull wire, as described herein, or by other means.

FIGURE 12 shows a hypotube 1150 into which slits 1155 have been cut. As can be seen, the slits are cut substantially parallel to the axis of the hypotube 1150. The portion of the hypotube between the slits 1155 forms the struts 1160. Because the slits are cut parallel to the axis of the hypotube, the struts themselves are parallel to the axis of the hypotube.

The slits 1155 are preferably cut by use of a laser upon the surface of a nitinol hypotube 1150 which forms a member of the shaft of the device. **FIGURE 12A** shows a lateral cross section of the slit hypotube 1150 of **FIGURE 12**. The radial disposition of the slits 1155 around the circumference of the hypotube 1160 can be seen. In the embodiment shown in **FIGURE 12A**, each slit is located about 60° from the next slit, and the width of each slit is about .002". Creating slits of the desired width requires controlling the width of the cutting beam of the laser to be approximately the same width as the slits to be cut. It will be appreciated that the number of slits cut (and hence the number of struts formed) need not be six as shown in **FIGURES 12** and **12A**, nor need the slits 1155 necessarily all be identically sized. Any number of struts may be formed, preferably between about 4 and 16, more preferably between about 6 and 12.

The length of the slits 1155 is sufficient that the struts 1160 which are formed will span the distance needed to reach the wall of the blood vessel being treated when the struts are moved into the expanded configuration. The struts are shown in the expanded configuration in **FIGURE 13**. The compression of the hypotube 1150 which results in the expanded configuration should not introduce bends in the struts severe enough to exceed the elastic capability of the hypotube material. If the elastic limit of the hypotube 1150 is exceeded, the struts 1160 may not

return to their original position (as shown in **FIGURE 13**) when the compression of the hypotube 1150 is relaxed, which may interfere with efficient removal of the device from the patient. Excessive bends may, in severe cases, cause the struts to crack or fracture completely, potentially harming the patient. The length of the slits, and hence the struts, is preferably between about .4" and .8", and more preferably between about .5" and .7".

Because integrally formed struts are simply a part of the distal end of one of the shaft members, struts formed in this way tend to have the lowest possible profile when in the collapsed configuration, since their collapsed configuration is simply a hypotube of the same diameter as the shaft with slits in it (see **FIGURE 12**). This is advantageous for facilitating easier introduction and removal of the filter assembly into the vasculature of the patient, as discussed above.

Integral Spiral Struts

In an alternate preferred embodiment, shown in **FIGURE 14**, struts 1162 are formed into the distal end of a hypotube 1150 by cutting slits 1157 on an angle to the central axis of the hypotube. By making the cuts angled, spiral struts are produced when the hypotube 1150 is compressed, as shown in **FIGURE 15**.

Generally, the process of creating the spiral struts 1162 is the same as the process described above for creating the straight struts shown in **FIGURE 13**. The slits 1157 are preferably cut by laser into a nitinol hypotube 1150. However, unlike the earlier embodiment, these struts are cut at an angle to the axis of the hypotube 1150.

One preferred design uses a hypotube 1150 with an outer diameter of about .016" and an inner diameter of about .010". The slits are about .002" wide, and the cuts are made at approximately a 5.48° angle to the axis of the hypotube. This angle used upon a hypotube of this size results in slits that will curve 360° around the hypotube about every .550". The section of the tube which is cut is about .675" long. Six slits are cut resulting in six struts.

By varying the angle of the slits and the size of the hypotube, different configurations can be achieved. An alternate design which also uses six slits and six struts spiral struts uses a hypotube of about .0132" outer diameter and about .0093" inner diameter with about .002" width slits at about a 4.74° angle. This results in slits that curve 360° in about .500". The cut length of the tube is about .675".

Another alternate embodiment uses the same size hypotube, but angles the slits about 9.42° from the axis of the tube. This produces slits which curve 360° in about .250", making for a tighter spiral shape.

In general, angles from about 3° to 40° are preferable, and angles between about 4° and 9° are more preferable for the angle between the axis and the slits cut into the tube. As above, any number of struts may be formed, preferably between about 4 and 16, and more preferably between about 6 and 12.

FIGURE 15 shows a spiral cut strut system in the expanded configuration. When subjected to either a compression or torsion force, the hypotube 1150 into which the slits 1157 are cut will bow outward, forming the spiral struts 1162 shown in the figure. The exact shape of the struts produced will depend upon the angle between the slits and the axis, the size of the hypotube, the number of slits cut into the hypotube, and the overall length of tube into which the slits have been cut. However, those skilled in the art will recognize that all such struts 1162 will

assume a spiral shape similar to that shown in **FIGURE 15** when deployed by appropriate compression or torsion in the cut region of the hypotube 1150.

A spiral strut may be desirable over a straight strut because of its better response to unevenly shaped blood vessels. As shown in **FIGURES 16A** and **16B**, the cross section of many blood vessels 1170 being treated will not be circular. Additionally, the central axis of the filter subassembly 1182 may not lie at the center of the blood vessel 1170 due to curvature of the blood vessel along its length. In either of these cases, a straight cut strut as described above may buckle and fail to properly expand the filter membrane so as to span the blood vessel.

FIGURE 16A shows a partial cross-sectional view of a straight cut strut system cut into a hypotube 1180 deployed off center in a blood vessel 1170. Because the straight struts formed by cutting slits into the hypotube 1180 expand radially based upon the amount of axial compression that they are subjected to, it is generally the case that each strut must expand by the same radial amount, since each is subject to the same amount of axial contraction.

However, when one or more of the struts is unable to expand fully in the radial direction because of the presence of the blood vessel wall 1175 or some other obstruction, the additional length generated by the axial compression must still result in some additional displacement. Often, this can result in a buckling condition where additional bends are introduced into the length of one of the struts. Such buckling can be seen in the strut labeled 1190 in **FIGURE 16A**. The strut 1190 needs to expand the same amount as the opposing strut 1192, because both are subject to the same compression. However, since the strut 1190 cannot expand further radially outward because of the blood vessel wall 1175, the strut 1190 has buckled and begun to expand radially inward away from the wall of the blood vessel 1175.

While this expansion in the buckled strut 1190 does allow the strut to accommodate the necessary axial compression, it results in a portion of the strut 1190 pulling away from wall 1175 of the blood vessel, and taking the attached filter membrane (not shown in **FIGURE 16A**) with it. This leaves an opening through which blood and embolic material may flow, allowing them to move around, rather than through, the filter membrane.

As shown in **FIGURE 16B**, such buckling and inward radial motion of the strut may develop further into the case where the buckling becomes so severe that the entire strut 1195 buckles through to simply flex inward, rather than outward, from the surface of the hypotube 1180. In these situations, significant portions of the blood vessel may not be properly occluded by the filter subassembly 1182.

Although a spiral strut system like that shown in **FIGURE 15** also expands radially in order to compensate for any axial compression to which it is subjected, spiral struts also produce rotational displacements along their length which account for some of the axial compression. These spiral struts therefore include both axial and rotational displacements along their length. As a result, when a spiral strut reaches a vessel wall or other obstacle which prevents further radial displacement of that strut, the strut will deflect in a rotational manner, rather than buckling radially. Because of this, the radial expansion can be less for one spiral strut than another, even when the axial compression is the same for both, as long as one strut has a different rotational path than the other.

As a result, a membrane which is supported by spiral struts can be made to span an irregularly shaped blood vessel or one which is not centered around the strut system without danger of buckling. By eliminating buckling in this way, gaps are prevented from developing in the coverage of the membrane across the vessel, and less opportunity for embolic material to bypass the filter is allowed.

Separately Formed Struts

In an alternative preferred embodiment, the struts are not formed integrally with a hypotube which is used as a shaft member, but instead are formed separately of ribbons of metal which are attached to the shaft near the distal end. Such an arrangement allows for different materials to be used for the shaft and struts, something which is often not possible when using integrally formed struts.

One means of producing a separate strut assembly is to follow the same procedure described above for forming struts by cutting slits in a hypotube, but to perform the procedure on a short length of hypotube which is separate from the shaft of the device. Once struts are formed on this short length of hypotube, it can then be bonded to the shaft using one of the methods described below.

One method involves creating the struts in a hypotube of larger diameter than the largest hypotube used in the shaft. Once slits are cut into the larger hypotube as described above for the integral strut systems, this strut hypotube is slid over the distal end of the shaft and its ends are bonded to different members of the shaft (to allow for actuation). Alternatively, a hypotube of similar diameter to that of the largest shaft member may be used, and the hypotube in which the slits are cut is fit to the distal portion of the largest shaft member end-to-end, while the distal end of the strut hypotube is attached to an inner shaft member.

The struts produced in this manner will have the same characteristics as those of the integrally formed struts described above. However, because they are made on a separate length of hypotube, several advantages can be derived. First, it becomes possible to make the struts from a different material from the shaft of the device. Particularly in situations where the flexibility of the strut material is unsuitable for use in the shaft of the device (or vice versa), this provides an advantage over the integrally formed struts. Each portion of the device can be manufactured using whatever strength and flexibility material that is best for that particular purpose, rather than attempting to find a single material which is suitable for both shaft and strut construction.

One preferred material for the struts described by this and other embodiments is a NiTi/Au composite material. Other materials may also be used, such as stainless steel, tungsten, platinum or other radiopaque materials, as well as other composite materials.

An additional benefit relates to the manufacturing process. Because the cutting process requires a high degree of precision, it is likely that some of the hypotubes will be improperly cut due to various factors beyond the control of the manufacturer. When integral struts are produced, if improper cuts are made, the entire hypotube may have to be scrapped, including at least some portion of the shaft portion. By cutting the slits onto a separate piece of tubing, any failure to produce sufficiently accurate cuts on the tube does not impact the production of the shaft in any

way. Particularly if the material used is expensive, a significant advantage may be derived by producing cut tube struts separately from the shaft tubing.

A different way to produce separately formed struts is to take separate ribbons of metal and to bond them directly to the shaft and guide tip. Although such a procedure involves more complexity than the previously described methods of producing struts, it also allows for the greatest possible freedom to create different strut geometry since there is no need for the material to form a single cylindrical surface initially.

The materials suitable for forming independent strut assemblies such as the cut hypotube subassemblies and the independent ribbon systems described above will generally be the same as those described as suitable for producing the integral struts and shaft described earlier. Specifically, super-elastic memory alloys, such as nitinol, as well as nitinol-stainless steel alloys, are preferable for such strut designs. The independent ribbon systems may be fabricated using a wider range of materials as there is no need for the initial form of the material to be a cylinder.

Once any struts are separately formed using one of the methods described above, they need to be attached to the shaft and guide tip of the device. Several different methods known in the art can be used for joining these metals together. Included among the preferred methods are crimping, heat fusing, soldering, and adhesive bonding.

'Hinged' Struts

In some cases, it will be desirable to produce acute, rather than gradual, bends in the struts used to support the membrane. In particular, this will be desirable when the geometry of the struts is sufficiently complex that it is desirable that a strut bend at a particular point, thereby preventing it from deforming at some other point where such a deformation might prevent proper occlusion of the blood vessel under treatment, or where bending at the other point would provide insufficient support to the filter membrane.

In preferred embodiments of the current invention, struts can be made to bend at particular points by creating 'hinges' at those points by specially treating the strut. Normally, the cross section of a strut is substantially constant over its length, producing a mechanical structure which will tend to distribute any stress throughout the length of the strut, resulting in constant, gradual deformation along the entire strut.

However, when it is desirable that the strut bends substantially or entirely at a specific point or points, it is possible to alter the cross section of the strut such that the altered region deforms more readily under stress, thereby alleviating the stress elsewhere in the strut and concentrating all deformation in one region. An example of this can be seen in **FIGURES 17A** and **17B**.

As shown in **FIGURE 17A**, one preferred method of producing such a hinge involves flattening a strut 1200 in the region 1210 which is desired to bend most. This technique, while applicable to any type of strut in theory, is more easily applied to struts which are formed independently and then mounted to a shaft. In particular, performing the flatting process upon a strut other than a separate ribbon strut will require additional manufacturing steps. This is because hypotube based struts will need to be actuated to expose the struts before any mechanical flattening can be applied to the strut.

When the strut 1200 is flattened by mechanically crimping the strut at a particular point, the cross section in the crimped region 1210 is less able to resist deformation across its narrowest width. This will also tend to make the strut wider at the crimped region, as shown in **FIGURE 17B**. Another method to alter the cross section of a strut so as to form a hinge is to cut notches into a strut.

As a result of flattening, this portion of the strut 1210 will bend more in response to any stress placed upon the strut, reducing the stress elsewhere in the strut and leaving it straight except for the flattened 'hinge' location. This can be seen in **FIGURES 18A** and **18B**. **FIGURE 18A** shows a crimped strut 1200 in which the entire bend occurs within the 'hinge' region 1210 of the strut. In **FIGURE 18B**, an unhinged strut 1220 is shown under the same total bending force. Because there is no flattened region, the bend is distributed throughout the length of the strut resulting in a gradually curved profile.

If desired, more than one such hinge may be created in a single strut to produce angled, rather than curved, strut geometry in the expanded configuration. This technique can be applied to either integrally formed or separately formed struts. Examples of strut designs using such hinge locations are shown in **FIGURES 19** and **20**.

ACTUATION

As described above, once a filter device is advanced to the point where the filter assembly lies just downstream of the region of the blood vessel to be treated, the filter subassembly is adjusted from its collapsed configuration into its expanded configuration. In order to achieve this adjustment, some form of actuation is used. The actuation may be triggered either by axial tension between two of the shaft members, or by axial torsion between two of the shaft members. These two types of actuation are referred to as 'tensional' and 'torsional' actuation.

Tensional Actuation

In a tension actuated strut mechanism, such as that shown in **FIGURE 21**, one shaft member is displaced along the axis of the shaft 1100 from at least one other shaft member. In the example in **FIGURE 21**, a pull wire 1110, which is also the core wire of the shaft, is pulled so that it is displaced proximally along its axis from a larger hypotube 1120. Because the pull wire is attached distally to the struts 1160, which are themselves attached to the hypotube 1120, an axial compression force is imposed upon the struts. As discussed with reference to strut design and **FIGURES 12-15** above, this axial compression results in the outward bending of the struts in order to alleviate the stress imposed upon the struts by the shortened pull wire.

To reverse this actuation and retract the struts, the pull wire 1110 is displaced distally so that it returns to its original relation with respect to the outer hypotube 1120 and the compression on the filter struts 1160 is eliminated. Once this stress is eliminated, the struts will return from the configuration shown in **FIGURE 21** to their original, collapsed configuration.

The same method of actuation described with relation to **FIGURE 21** above can also be accomplished by holding the core wire 1110 in position and pushing the hypotube 1120 distally over it. This produces the same relative displacement between the core wire 1110 and hypotube 1120 as described above, and results in the same axial

compression and strut deployment. Such actuation may be reversed by pulling the hypotube 1120 proximally relative to the core wire 1110.

An alternate means of accomplishing a tensional actuation is by displacing an outer sheath proximally so that it uncovers a filter subassembly. This can be seen in **FIGURE 21A**. The sheath may be formed by adding an additional hypotube 1230 around the hypotube 1220 upon which the struts 1260 are formed. If the filter subassembly is constructed so that the struts 1260 have a bias to move to the expanded configuration (shown in **FIGURE 21A**), the struts 1260 will expand once the sheath 1230 no longer restricts this expansion.

Such a bias is shown in **FIGURES 21A** and **21B** through the use of a tension spring 1250 which pulls the ends of the filter subassembly together. The proximal end of the tension spring 1250 is preferably attached to an anchor plug 1240 which is fixed within the strut-bearing hypotube 1220. The distal end is preferably attached to the distal plug 1270 at the distal end of the struts 1260. A guide tip, as described above, may be used distal of the distal plug 1270, but is not shown.

An advantage of the embodiment described above and shown in **FIGURES 21A** and **21B** is that no pull wire is needed in order to actuate the struts 1260. Because the necessary actuation force is provided by the tension spring 1250, the filter subassembly is self-actuating. It will be appreciated that the member 1220 need not be hollow, but may be solid with the tension spring distally attached thereto. This simplifies manufacture of the shaft significantly.

Additionally, because the bias is being provided by a separate tension spring 1250, in one embodiment, there is no need to use a shape-memory or super-elastic alloy for the composition of the struts 1260. The struts may be manufactured out of any material of appropriate stiffness to bow outward under compression force, without concern of whether or not it can be made to exhibit a bias to a particular configuration. Furthermore, the spring 1250 may be made out of a material such as stainless steel, which exhibits little or no shape memory or super-elasticity.

Means other than a tension spring may also be used to provide the necessary bias, such as initially constructing the struts in a curved or bent shape using a shape memory alloy (as shown in **FIGURES 21C** and **21D**), or other means known in the art. To return the filter subassembly to the collapsed configuration, the outer hypotube 1230 is pushed distally, pressing against the struts 1260 and forcing them back inside the sheath 1230 and returning the filter subassembly to its collapsed configuration, shown in **FIGURE 21B**.

Although these actuation methods are shown in use upon an integrally formed strut system with straight struts, it will be understood by those skilled in the art that these methods can be applied equally well to struts with other than straight geometry, as well as to separately formed struts and other configurations.

FIGURES 21C and **21D** illustrate another embodiment similar to **FIGURES 21A** and **21B**, in which a filter subassembly has struts 1260 which are preset or shaped in a desired expanded configuration. When the struts are ejected out of the hypotube 1230, the struts expand to their relaxed position, i.e., the expanded configuration. The filter is retracted by pulling proximally on the inner hypotube 1220 to pull the struts 1260 into the outer hypotube 1230.

Another alternative means of producing a tensional actuation is to place flanges on each strut which project into the lumen of the member on which they are formed. A push rod member is disposed within the lumen of the member upon which the struts are formed, and is disposed proximal of the flanges when the system is in the collapsed configuration. By displacing the push rod distally, the end of the push rod will press against the flanges of the struts, which will cause them to displace radially, extending the struts into the expanded configuration. By forming the struts with a bias toward the collapsed configuration, the process is reversed simply by displacing the push rod proximally such that it no longer forces the flanges to displace radially.

Torsional Actuation

In a torsion actuated strut mechanism, such as that shown in **FIGURES 22A** and **22B**, one shaft member is rotated about the axis of the shaft with respect to at least one other shaft member. As illustrated in **FIGURE 22A**, a core wire (not shown) is connected to the distal end 1152 of the hypotube 1150 from which the struts 1162 are formed. The core wire is twisted so that it rotates with respect to the hypotube 1150 of the shaft. Because the core wire is attached to the distal end 1152 of the struts and the proximal end 1154 of the struts is part of the hypotube 1150, this sets up a torsional stress within the strut system. In response to this stress, the struts 1162 will displace radially into the expanded configuration, as shown in **FIGURE 22B**.

Unlike the purely tensional mechanisms described above, pure torsional actuation cannot be used effectively on struts which are purely straight and parallel to the axis of the shaft, as these struts develop no rotational displacement when deployed. However, for any curved or spiral strut system, torsional actuation produces the desired effect.

It is possible to actuate purely straight struts using a torsion mechanism if this torsional motion results in a tensional stress upon the straight struts. A means of accomplishing this is to attach the proximal end of the struts to the distal end of a collar, formed of a short length of hypotube. The collar is itself connected proximally to the shaft of the device using a screw thread arrangement, such that the collar is screwed onto the end of the shaft. The distal end of the struts is connected to the core wire and guide tip as described above.

When the core wire is rotated, it will cause the struts to rotate, and hence the collar to rotate as well. This rotation will cause rotation between the collar and the shaft, which will cause the collar to displace axially as it is unscrewed from the shaft. This axial motion will set up the necessary compression stress in the struts to cause them to deploy into the expanded configuration.

In any of the above torsional arrangements, the core wire is simply rotated in the opposite direction used to actuate the struts in order to return to the collapsed configuration. This eliminates the stresses which caused the radial bowing of the struts 1162, and the struts will relax into their original configuration shown in **FIGURE 22A**.

It is also possible to combine both torsional and tensional actuation in cases where this provides an advantage. Each filter subassembly used in a given embodiment of the present invention must be deployed through some actuation means. In every case, some form of actuation is needed in order to trigger the struts of a particular filter subassembly to move into the expanded configuration, or back into the collapsed configuration. However, it is

possible that more than one filter subassembly may be controlled through the use of the same actuation method. When multiple filter subassemblies are deployed or retracted through the use of a single actuation step, this is referred to as "single actuation". When different filter subassemblies require separate, independent actuation steps, this is referred to as "double actuation" in the case where there are two independent actuating steps for at least two filter subassemblies, or more generally "multiple actuation" when there are at least two independent actuation steps for at least two filter subassemblies.

ADDITIONAL EXEMPLARY EMBODIMENTS

Following are descriptions of four examples of preferred embodiments of the current invention, made in reference to **FIGURES 23-26**. Although these examples demonstrate a variety of different strut systems, as well as different arrangements of strut systems and membrane locations, they are not exhaustive and do not represent the full spectrum of variation which is within the scope of the present invention. These examples are intended merely to illustrate, and not to limit, the breadth of the current invention.

Single Actuation, Single Strut System, Single Filter Membrane

One example of a preferred embodiment of the present invention is shown in **FIGURE 23**. In this embodiment the filter subassembly 1300 comprises a single strut system 1350 used to support a single filter membrane 1330 which is located on the outside of the distal portion of the struts. An outer hypotube 1320 in which slits have been cut forms integral straight struts when actuated, and a core wire 1310 is disposed inside the hypotube 1320 and acts as a pull wire.

A single tensional actuation controls the configuration of the strut system 1350. By pulling on the core wire 1310 relative to the outer hypotube 1320, compression in the slit region of the hypotube causes the struts to extend radially into the expanded configuration (as shown in **FIGURE 23**). The struts shown have hinges midway along their length, as indicated by the abrupt angle formed in the strut at the edge of the filter membrane 1330.

A distal guide tip 1340 is located at the distal end of the device. The guide tip comprises a core wire (not shown) which is wrapped in a coil of thinner wire 1360 and a rounded tip 1370.

Single Actuation, Single Strut System, Double Filter Membrane

Another example of a preferred embodiment of the present invention is shown in **FIGURE 24**. This embodiment makes use of the same core wire 1310 and hypotube 1320 as shaft members as does the previous embodiment. It also makes use of the same single tensional actuation mechanism operating between the core wire and the hypotube as the previous embodiment. This results in a deployment of the single strut system 1350.

However, unlike the previous embodiment, **FIGURE 24** shows a device which makes use of continuously curved (unhinged) struts and also includes two filter membranes located at different positions upon the strut system 1350. In the shown system, a first filter membrane 1380 is located on the proximal or upstream portion of the strut system on the outside of the struts. A second filter membrane 1390 is located on the distal or downstream portion of the strut system 1350 on the outside of the struts.

The size of the openings in the filter membranes may differ between the first membrane 1380 and the second membrane 1390. In the design illustrated in **FIGURE 24**, the pore size of the upstream filter membrane 1380 will be larger than that of the downstream filter membrane 1390 so as to more effectively filter embolic matter from the blood. Large embolic matter which is greater in size than the size of the pores in the first filter membrane 1380 will be trapped by the first filter membrane. This embolic material must be removed from the blood vessel by aspiration before the strut system is retracted into its collapsed position. Failure to do so will release this material into the blood stream when the filter is collapsed.

Any embolic material which is small enough to flow through the pores in the first filter membrane 1380, but larger than the pores in the second filter membrane 1390 will travel through the first membrane and be trapped by the second membrane, within the confines of the strut system 1350. This material generally cannot be removed from the filter subassembly 1300 by aspiration due to the presence of the first filter membrane 1380 which will tend to interfere with the aspiration of particles within the strut system 1350. However, particles within the strut system will be trapped there when the strut system is retracted from the expanded configuration shown in **FIGURE 24** into its collapsed configuration, and so may be removed along with the occlusion device itself.

Single Actuation, Double Strut System, Double Filter Membrane

Another alternate embodiment shown in **FIGURE 25** also makes use of two filter membranes 1380, 1390, but mounts them on separate strut systems. A core wire 1310 is still used and the shaft is still formed from an outer hypotube 1320. However, rather than the integrally formed struts as shown in the embodiments of **FIGURES 23** and **24**, the embodiment of **FIGURE 25** makes use of separately formed ribbon struts.

FIGURE 25 shows a first strut system 1400 mounted to the distal end of the hypotube 1320. This strut system has a first filter membrane 1380 disposed on the outside of the distal portion of the struts. The distal end of the first strut system 1400 is attached to an intermediate shaft member 1410 of the same diameter as the outer hypotube 1320. Mounted on the distal end of the intermediate shaft member 1410 is a second strut system 1420. The distal end of the second strut system is attached to the distal end of the core wire 1310. A second filter membrane 1390 is disposed on the outside of the distal portion of the second strut system 1420. Both the first strut system 1400 and the second strut system 1420 use separate ribbon struts which are attached to the tubes to form the separate strut systems.

A single tensional actuation mechanism is also used in the embodiment shown in **FIGURE 25**. However, when the core wire 1310 is pulled with respect to the outer hypotube 1320, both the first 1400 and the second 1420 strut systems will be deployed into the expanded configuration. This is because pulling on the core wire 1310 sets up a compression force in both the first and second strut systems at the same time. As a result, both strut systems will deploy, and both will retract in response to the same actuation. This is an example of a single actuation being used for the multiple strut systems.

As described with reference to **FIGURE 24**, the first filter membrane 1380 and the second filter membrane 1390 may have different pore sizes. It is still the case that generally the larger pore size membrane will be used as the

first filter membrane 1380, as it is located upstream of the second filter membrane 1390 within the blood vessel. However, an advantage of the current embodiment is that the first filter membrane need not be aspirated before the strut systems are returned to the collapsed position. This is because unlike the previous embodiment, the first filter membrane 1380 is located on the distal portion of the first strut system 1400, so the embolic material trapped by this membrane will be held within the membrane and within the strut system when the struts are retracted. Because both the first and second membranes are mounted in this way, neither absolutely requires aspiration before retraction and removal from the patient.

Double Actuation, Double Strut System, Double Filter Membrane

A final example preferred embodiment is presented in **FIGURE 26**. The most significant difference between this embodiment and the embodiment of **FIGURE 25** lies in the use of a three member shaft 1450. This shaft comprises a central core wire 1310, an outer hypotube 1320, and also a middle hypotube 1430. The general design of this shaft is shown in **FIGURE 26A** and described below.

An example of an alternative design for the shaft is shown in **FIGURE 26A**. Although the shaft design illustrated in **FIGURES 26** and **26A** is different from the shaft design used in the previously discussed embodiments, those skilled in the art will recognize that variations in the number and size of members used in the shaft are possible within the scope of the present invention.

FIGURE 26A shows a partial cut-away view of an alternate shaft 1100 making use of three elongated cylindrical members. The core wire 1110 is shown disposed coaxially with a middle member 1120 formed of a hypotube. The core wire lies within the lumen 1125 of this middle hypotube. Both the core wire and middle hypotube are disposed coaxially within an outer member 1130 formed from a hypotube as well. The middle member and core wire lie within the lumen 1135 of the outer hypotube. Disposed around the circumference of the outer hypotube 1130 are a number of holes 1140.

As shown in **FIGURE 26A**, the shaft 1100 may also comprise holes 1140 cut into the tubular members proximal of the filter subassembly (not shown). These holes are preferably located in the middle of the length of the shaft, although for some purposes they may be located closer to the distal end of the shaft. The holes may be formed by conventional drilling, electron discharge machining (EDM) or laser drilling.

These holes 1140 serve as a path between the blood flow within the vessel being treated (not shown) and the inner lumen 1135 of the member 1130 in which they are located. These holes may serve as a path for the aspiration of embolic matter from the blood vessel. To be used for this purpose, the holes must be larger than the size of the embolic particles to be aspirated. Generally this means that the holes must be larger than the openings of the filter membrane, since the filter membrane openings determine the minimum size embolic particle which will be trapped by the filter.

Another use of these holes is to allow the introduction of medication into the treatment site. Such medication could include heparin solutions or other antithrombogenic treatments used in order to prevent blood clots from forming upon the surface of the device. Such clots, particularly if formed upon a portion of the device intended to

flex or move, such as the 'hinges' of the struts, might undesirably interfere with the proper deployment and operation of the device.

Shafts, such as those shown in **FIGURE 26A**, which make use of more than two members, may be used in conjunction with certain embodiments of the present invention. For example, embodiments which make use of multiple filter subassemblies which are capable of independent deployment may employ multiple shaft members. An example of such an embodiment is shown in **FIGURE 26** and will be discussed below. Designs in which aspiration means or medication delivery means are incorporated with the occlusion device may also incorporate additional shaft members. They may be used to introduce medication into the bloodstream through the lumen of an additional member, or in the case of aspiration catheters, to extract blood and embolic matter from the bloodstream through the lumen of an additional member. Additional outer members might also be added in order to provide a cover for the device, or for use as a retrieval sheath.

Referring to **FIGURE 26**, two strut systems are located distally upon the above described shaft 1450: the first 1400 is located at the distal end of the outer hypotube 1320; the second 1420 is located at the distal end of the middle hypotube 1430. The distal end of the first strut system 1400 is attached to the middle hypotube 1430, and the distal end of the second strut system 1420 is attached to the core wire 1310. A first filter membrane 1380 is located on the outside of the distal portion of the struts of the first strut system 1400, and a second filter membrane 1390 is located on the outside of the distal portion of the struts of the second strut system 1420.

Because a three-member shaft 1450 is used, independent actuation is possible for the first strut system 1400 and the second strut system 1420. This is an example of "double actuation" as described above. In order to actuate the first strut system 1400 into the expanded configuration (as shown in **FIGURE 26**), the middle hypotube 1430 is pulled proximally relative to the outer hypotube 1320. The core wire 1310 will generally be pulled along with the middle hypotube 1430 so that no relative motion is produced between the core wire and middle hypotube. The motion of the middle hypotube 1430 relative to the outer hypotube 1320 will set up a compression force in the first strut system 1400, but not in the second strut system 1420. Consequently, the first strut system will deploy into the expanded configuration, but the second strut system 1420 will not.

In order to actuate the second strut system 1420, the core wire 1310 is displaced proximally relative to the middle hypotube 1430. As long as the middle hypotube is not displaced with respect to the outer hypotube 1320 during this process, no effect will be had on the compression force in the first strut system 1400, and hence no actuation of the first strut system will take place. However, this relative motion between the core wire 1310 and the middle hypotube 1430 will result in a compression force within the second strut system 1420, which will cause the second strut system 1420 to deploy into the expanded configuration. **FIGURE 26** shown both the first and second strut systems in their expanded configurations.

Because it is independently possible to actuate each strut system, it is possible to configure the embodiment of **FIGURE 26** with either both filters in the expanded configuration (as shown), both filters in the collapsed configuration (used for insertion and withdrawal of the device from the patient), with the first filter expanded and the

second collapsed, or with the first filter collapsed and the second filter expanded. This final configuration is advantageous because it allows for the aspiration of the second filter membrane 1390.

In the previously described double membrane systems of **FIGURES 24** and **25**, the second filter membrane would be difficult to aspirate through the use of an aspiration tube which is inserted over the shaft. This is because in both cases, the first filter membrane 1380 would always interfere with aspiration since the first strut system 1400 would always be in the expanded configuration whenever the second strut system 1420 was in the expanded configuration. Because both of these embodiments used single actuation methods, there was no way to collapse the first strut system while leaving the second strut system expanded.

However, with the independent control which double actuation in the embodiment of **FIGURE 26** allows, it is possible to collapse the first strut system 1400 by pulling the outer hypotube 1320 with respect to the inner hypotube 1430, without collapsing the second strut system 1420. Once the first strut system is collapsed, an aspiration catheter can be advanced over the shaft and first strut system in order to properly aspirate embolic material from the second filter membrane 1390 and second strut system 1420.

FURTHER FILTER EMBODIMENTS

Another embodiment of the invention is illustrated in **FIGURE 27A**, in which an expandable member 2100 is shown in its deployed, expanded configuration within a vessel 2104 such as a blood vessel. In its deployed configuration, the expandable member 2100 extends throughout the vessel 2104 in the radial direction. If the expandable member 2100 is self-expanding, it may be deployed by retracting a sheath 2106 which surrounds the expandable member, thereby allowing the expandable member to expand. On the other hand, if the expandable member 2100 is not self-expanding, then a pull wire (not shown in **FIGURE 27A**) may be used to deploy the expandable member 2100. (In this case, the pull wire could be secured to the distal end of the expandable member 2100, pass through the expandable member, and exit the expandable member at its proximal end. One such pull wire arrangement is shown and discussed below in connection with **FIGURES 32** and **33**.) The expandable members disclosed herein are preferably non-inflatable, mechanical devices and may be designed to be either self-expanding or non-self-expanding, so that they can be deployed using either a sheath or a pull wire, respectively. An expandable member which is non-self-expanding tends towards its relaxed, undeployed position in the absence of an external force, such as the tension from a pull wire. A self-expanding expandable member, on the other hand, has the tendency to remain in the deployed position unless acted upon by an external force, such as that provided by a sheath.

The expandable member 2100 includes a plurality of ribbons 2108 as well as a membrane 2112 that covers the ribbons at their distal ends. The ribbons 2108 may advantageously be formed from Ni-Ti, stainless steel, or elgiloy, and have a length between 6 mm and 30 mm, and more preferably between 15 and 25 mm. The cross section of the ribbons 2108 may advantageously be 0.003-0.020" in one dimension by 0.009-0.040" in the other. The number of ribbons 2108 is preferably between 4 and 8, although more or fewer ribbons may be used.

The membrane 2112 may advantageously include a plurality of holes 2116, whose size is chosen such that blood may pass through the holes as blood travels through the vessel 2104 in a distal direction, whereas emboli in the

blood are too large to pass through the holes and are thereby contained. The emboli are captured by that surface of the membrane 2112 facing the blood as blood flows in a proximal to distal direction, i.e., the proximally facing surface. The membrane 2112 as well as the other membranes disclosed herein may be PET or an elastomeric or plastic material having holes between 20 and 300 microns in diameter, and more preferably between 50 and 100 microns in diameter. (Alternatively, for some applications, it may be preferable to use non-porous membranes.) The expandable member 2100 and the other expandable members disclosed herein advantageously make a seal with the vessel 2104 so that emboli cannot pass distal of the expandable member 2100. To this end, the radial expansion of the ribbons disclosed herein may be facilitated by advantageously imparting an initial curvature to the ribbons through heat setting.

Thus, the expandable members herein act as perfusion-filter devices which may be advantageously used in conjunction with a therapy procedure that generates emboli (such as angioplasty or another vascular procedure), i.e., the expandable members allow for the *perfusion* of blood while simultaneously *filtering* or capturing emboli and other particulates. For example, a perfusion-filter device may be positioned distal to a segment of a vessel to be treated, and then deployed. The expandable member is advantageously adjustable between a retracted position and a deployed position, in which the cross section of the expandable member in its retracted position permits the device to pass through and be positioned within the vessel, whereas the cross sectional profile of the expandable member in its deployed position substantially matches that of the cross sectional profile of the vessel, permitting the vessel to be sealed. A therapy catheter may be deployed near or at the site to be treated, and therapy may be performed on the vascular segment. The expandable member filters out or captures emboli generated during or after treatment while permitting the perfusion of blood through the expandable member during the treatment procedure. Following treatment of the vessel, the treated site may be aspirated and/or irrigated, and the expandable member (and the elongate member or catheter to which it is attached) may be retracted, and the perfusion-filter device may be removed from the patient.

Operably coupled to the expandable member 2100 is a radiopaque element 2118, which in **FIGURE 27A** is illustrated in the form of material which has been plated or crimped onto the ribbons 2108 near or at their point of maximum radial extent, e.g., a gold or platinum layer having a thickness of 0.001-0.005" and a length of 0.005-0.050" may be formed on the ribbons 2108. Alternatively, radiopaque strips (not shown) that are approximately equal in length to the ribbons 2108 may be joined to the ribbons 2108 so radiopaque material extends along the entire length of the ribbons 2108. The radiopaque element 2118 allows the user to monitor the radial position of the expandable member 2100 as the expandable member is deployed, thereby giving the user an indication as to how completely the expandable member has been deployed. The radiopaque elements herein may be gold or platinum and are preferably located adjacent the wall of the vessel 2104 when the expandable member is in the deployed position. The relationship between the vessel 2104, the membrane 2112, the ribbons 2108, and the radiopaque elements 2118 secured to the ribbons is also shown in the cross sectional view of **FIGURE 27B.**

The expandable member 2100 is advantageously connected to (e.g., bonded or crimped) or integrally formed with both an elongate member 2120 and a distal tip 2124. A core wire 2125 (e.g., stainless steel or nitinol) may advantageously reside within the distal tips disclosed herein to enhance the structural integrity and mechanical

stability of the devices. In **FIGURE 27A**, the core wire 2125 is joined to the distal end of the tip 2124 by a solder joint 2126; the core wire 2125 may be advantageously joined to the proximal end of the tip 2124 using, for example, another solder joint (not shown). The elongate member 2120 and the other elongate members disclosed herein may advantageously include a nickel-titanium alloy (such as Nitinol), elgiloy, stainless steel, braided plastic, or a composite material such as NiTi/stainless steel; they may advantageously have wall thicknesses of between 0.002 and 0.004", and have an O.D. of less than about 0.038", and more preferably an O.D. of about 0.014". The ribbons 2108 are joined at their proximal end to the elongate member 2120, at which point the O.D. of the device may advantageously be between about 0.018 and 0.025". The distal tip 2124 (as well as the other distal tips disclosed herein) preferably includes radiopaque material and may have a length between 25 and 50 mm and an O.D. of between 0.014" and 0.030". By moving the elongate member 2120 in the longitudinal direction through the vessel 2104, the user can position the expandable member 2100 within the vessel. The distal tip 2124 facilitates proper placement of (i.e., guides) the expandable member 2100 as the expandable member is positioned within the vessel 2104, as is well known in the art.

The ribbons 2108 may be pre-bent or weakened at various points so that the ribbons are urged to seal with the vessel 2104 at those points where the ribbons have been weakened, rather than along the entire length of the ribbons, which might not result in a good seal with the vessel. This is illustrated in **FIGURE 27C**, which does not show radiopaque elements or a membrane for the sake of clarity. In **FIGURE 27C**, a plurality of ribbons 2108' having respective bends therein are shown, in which the ribbons are urged towards the vessel wall 2104 at the bends of the ribbons. In the embodiment of **FIGURE 27C**, a radiopaque member is preferably in proximity with the bends of the ribbons 2108', and a membrane 2112 (which may advantageously include a plurality of holes) surrounds the ribbons 2108' at their distal ends.

The expandable member may alternately include a braid, a plurality of coils, a slotted tube, or a filter-like mesh, and is preferably formed from a memory shape material such as superelastic Ni-Ti or another elastic material that is likewise bonded, crimped, or integrally formed with both an elongate member and a distal tip. In **FIGURE 28A**, an expandable member 2200 includes a braid 2208. When the braid 2208 expands as illustrated in **FIGURE 28A**, emboli within the vessel 2104 are blocked from travelling distal of the expandable member 2200. The emboli may be blocked by the braid 2208 itself if the braid is formed tightly enough, or the emboli may be blocked by a membrane 2212 that surrounds the braid 2208 at its distal end. On the other hand, the braid 2208 may be woven loosely enough to permit blood to perfuse through the braid 2208. Likewise, the membrane 2212 (if one is used) may advantageously contain holes 2216 therein to permit the perfusion of blood while trapping emboli. Within the braid 2208 there is interwoven one or more radiopaque strands 2228, such that as the expandable member 2200 expands, the radial extent of the expandable member can be monitored. For example, 1, 2, or 3 platinum or gold wires (0.001-0.003" thick) may be interwoven among between 8 and 32 strands of Nitinol or stainless steel. Alternatively, radiopaque ribbon may be combined with the braid 2208. The overall elasticity of the device may be reduced somewhat by the presence of platinum or gold, however. As in the embodiment of **FIGURE 27A**, the expandable member 2200 may be

advantageously connected to or integrally formed with an elongate member 2220, as well as a distal tip 2224, with the distal tip preferably being formed from a radiopaque material.

FIGURE 28B shows a braid embodiment similar to the one of **FIGURE 28A**, except that the one or more radiopaque strands 2228 extend throughout the expandable member 2200 in the radial sense (as opposed to the longitudinal orientation of **FIGURE 28A**). The radiopaque element 2228, and the other radiopaque elements disclosed herein, may be advantageously located near the radial extent of the expandable member to indicate the extent to which the expandable member is deployed.

Radiopaque strands 2228 are also used in connection with the embodiment of **FIGURE 28C**, which is similar to the embodiments of **FIGURES 28A** and **28B**, with a filter-like mesh 2209 being used instead of a braid 2208 to form an expandable member 2201. Like the braid 2208, the filter-like mesh 2209 may be made of narrow strands of memory material (such as Nitinol, elgiloy, or stainless steel), although the strands of the mesh 2209 are generally ordered more randomly than those in the braid 2208. The mesh 2209 may thus be constructed to act as a perfusion-filter without the need for a membrane, although a membrane with holes therein may be used in conjunction with the mesh 2209. Either the braid 2208 or the mesh 2209 may be used without a membrane if the strands making up the braid or the mesh are sufficiently dense--in this sense, the braid and the mesh may be regarded as having pores.

Another perfusion mesh embodiment is illustrated in **FIGURES 29A** and **29B**, in which an expandable member 2300 includes a plurality of coils 2308 which are shown in their expanded configuration within the vessel 2104. A 2310 wire may advantageously run through the center of each of the coils 2308 to enhance the mechanical integrity of the expandable member 2300. A membrane 2312 covers the coils 2308 distal to where the expandable member 2300 seals with the vessel 2104. The membrane 2312 has a plurality of holes 2316 therein for permitting the perfusion of blood while trapping emboli, thereby preventing them from travelling downstream of the expandable member 2300. Like the other expandable members disclosed in **FIGURES 27-30**, the expandable member 2300 advantageously makes a seal with the vessel 2104. In particular, the membrane 2312 contacts the wall of the vessel 2104 to prevent emboli from migrating downstream. A radiopaque element 2328 in the form of a cylindrical element (such as a sheath) is placed around each of the coils 2308 and surrounded with a heat-to-shrink material 2332. When the material 2332 is heated, the material 2332 collapses onto the radiopaque element 2328, so that the material 332, the radiopaque element 2328, and the coil 2308 are held firmly together. The radiopaque elements 2328 are preferably positioned along the coils 2308 such that as the expandable member 2300 is deployed, the radiopaque elements are located near the maximum radial extent of the coils 2308, thereby allowing the user to monitor the extent to which the expandable member 2300 is deployed. The expandable member 2300 adjoins an elongate member 2320 at one end and a distal tip 2324 of radiopaque material at the other end, as in the other perfusion-filter embodiments. As an alternative to using the radiopaque elements 2328, the wires 2310 themselves may be radiopaque.

Another perfusion-filter embodiment is illustrated in **FIGURE 30**, in which an expandable member 2400 includes a slotted tube portion 2408. At the proximal end of the slotted tube portion 2408 is an elongate member 2420 (e.g., a wire or a hypotube), and at the distal end of the slotted tube portion is a distal tip 2424. The elongate

member 2420 (and the distal tip 2424) can be joined to the slotted tube portion 2408 by press fitting, crimping, or joining them together.

The distal tip 2424 may advantageously include a radiopaque material, and may be constructed at least in part from stainless steel, platinum, or Nitinol, or a combination thereof. As in other perfusion-filter embodiments disclosed herein, the distal end of the expandable member 2400 includes a membrane 2412 having holes 2416 which allow for the perfusion of blood while containing emboli. Further, the expandable member 2400 is joined with a radiopaque element 2428, which is illustrated in **FIGURE 30** as being material which has been plated onto the slotted tube portion 2408, e.g., a gold or platinum layer may be formed on the slotted tube portion. However, other radiopaque elements may be used with the expandable member 2400, such as one or more wires (cf. **FIGURES 28A, 28B, and 28C**) or material which held in place by a heat-to-shrink material (cf. **FIGURE 29**).

Likewise, all of the expandable members illustrated in **FIGURES 27-30** and those described further below may be combined with one or more of the radiopaque elements illustrated herein, such as one or more radiopaque wires, a layer of radiopaque material (which may be a layer that has been formed by plating (see **FIGURES 27 and 30**), or, for example, it may be a layer within the interior of the expandable member (not shown in the figures)), or radiopaque material sandwiched between an expandable member and a heat-to-shrink material. In one example, the radiopaque element may be a coating of gold, tungsten, platinum or other material applied over the entire length of the ribbon or strut 108, preferably using electroplating. In another example, a foil of gold, tungsten, platinum or other material may be placed along the length of the struts.

Thus, the embodiments illustrated in **FIGURES 27-30** should be considered exemplary, and not limiting, with respect to what kind of radiopaque element can be used with an expandable member. In addition, other techniques may be used to join a radiopaque element to an expandable member. For example, an expandable radiopaque ring (not shown) may be crimped or adhesively bonded to the expandable member. Further, the expandable member may be formed from a composite material such that the radiopaque element and the expandable member are integrally formed. So that the profile of the radiopaque element does not differ significantly from that of the expandable member, the expandable member may have a groove or undercut region (not shown) for receiving the radiopaque element, resulting in a uniform profile of the expandable member/radiopaque element combination. The wall thickness of the ribbons 108, for example, may be reduced by etching, coining, or grinding. In all of the perfusion-filter embodiments disclosed herein, the radiopaque element on the expandable member allows the user to monitor the radial position of the expandable member as the expandable member is deployed, thereby giving the user an indication as to how completely the expandable member has been deployed.

In the embodiment illustrated in **FIGURE 30**, the expandable member 2400 is self-expanding and deployed by retracting (pulling in the longitudinal direction) a sheath 2440 which surrounds the expandable member prior to its deployment. The slotted tube portion 2408 has a natural tendency to expand, and may be advantageously "shape set" for this purpose. Thus, as the sheath 2440 is retracted, the expandable member expands to seal with the vessel 2104, thereby preventing emboli from travelling downstream of the expandable member 2400. The slotted tube

portion 2408 may be advantageously shape set by expanding it out (e.g., with a mandrel), and then heating it at 300-700 degrees C for between 10 seconds and 30 minutes.

The membranes 2112, 2212, 2312, and 2412 of **FIGURES 27-30** may be formed, for example, by a vacuum forming process, by heat forming a plastic (such as PET), or by a dipping process. One such dipping process is outlined in **FIGURES 31A** and **31B**, illustrated in connection with the expandable member 2100 which includes the ribbons 2108. As shown in **FIGURE 31A**, the ribbons 2108 are inserted into a container 2500 that holds a suitable membrane forming material 2504 such as polyurethane, silicone, or a suitable plastic. If need be, a mechanical restraint such as a slug (not shown) may be placed between the ribbons 2108 to keep them in an expanded position while they are being coated. The ribbons 2108 may be advantageously inserted such that a roughly hemispherical fraction of the ribbons is covered. As indicated in **FIGURE 31B**, the membrane forming material 2504 dries to form the membrane 2112. Holes may be formed in the membrane 2112 with a laser beam, such as an excimer laser, for example. Although no radiopaque element is shown in **FIGURE 31A** or **31B**, the ribbons 2108 may be advantageously joined with a radiopaque member prior to the dipping process.

FIGURE 32 shows an embodiment in which an expandable member 2600, an elongate flexible section 2604, and a distal tip 2608 are integrally formed out of a single hypotube 2612. Such a device 2616 may be constructed by using a laser beam or EDM to drill away portions of the hypotube 2612 to form the appropriate section. For example, the distal tip 2608 may be formed with a laser by cutting away parts of the hypotube 2612 to leave a spiral-like tip. The expandable member 2600 may likewise be formed by cutting slits 2620 in the hypotube to leave a section that can be radially expanded to match the contour of a vessel. Although the slits 2620 are shown as being longitudinal, it will be understood that they could be at an angle with respect to the longitudinal axis, e.g., the slits 2620 may form a spiral. The elongate flexible section 2604 may advantageously include one or more slits 2624 to increase the flexibility of the elongate member, thereby aiding the user as the device 2616 is guided through a vessel, although for some applications these slits 2624 may not be necessary.

Also indicated in **FIGURE 32** is a pull wire 2628 that runs along the length of the device 2616 and is joined directly or indirectly to a distal portion of the device 2616. The pull wire 2628 is joined to the distal tip 2608 by solder joints 2630 and 2631 at the distal and proximal ends of the tip 2608, respectively, so that the tip 2608 maintains its orientation when the pull wire 2628 is retracted. Alternatively, the pull wire 2628 may be crimped to the hypotube 2612, in addition to or instead of soldering, at location 2631. By retracting the pull wire 2628 (pulling it in the longitudinal direction), the expandable member 2600 is deployed from its retracted position. The distal end portion of the pull wire 2628 may advantageously include radiopaque markers 2650 thereon which are discussed below in connection with **FIGURE 33**.

The expandable member 2600 is shown in its deployed configuration in **FIGURE 33**, along with a membrane 2632 having holes 2636 therein which contain emboli while allowing the perfusion of blood. A radiopaque element 2640 is also shown in **FIGURE 33** which indicates the radial extent of the deployment of the expandable member 2600. Perfusion of blood is possible in that blood may pass through the slits 2624 or 2620 and then pass out through

the holes 2636 in the membrane 2632, whereas emboli and other particulates are advantageously captured by the holes 2636.

The radiopaque markers 2650 may be platinum or gold and can be secured to the pull wire 2628, e.g., by crimping or adhesive bonding. The radiopaque markers 2650 indicate the location of the pull wire 2628 within the vessel 2104. The markers 2650 may be used, for example, to ascertain the length of a lesion. Also, the markers 2650 may serve as landmarks to aid in the accurate positioning of a therapy catheter or device, such as a stent, delivered over the hypotube 2612. Further, the markers 2650 may assist the user in the proper deployment of the expandable member 2600 by correlating the axial movement of the pull wire 2628 with the radial expansion of the expandable member 2600. This can aid the user in those situations, for example, when further retraction of the pull wire 2628 does not result in any further radial movement of the radiopaque element 2640. Such a circumstance might indicate to the user that the device has malfunctioned or that the user is exerting excessive force on the vessel. Pull wires having radiopaque markings may also be used with the other embodiments disclosed herein.

The elongate flexible section 2604 of **FIGURES 32** and **33** may advantageously be from 5 cm to 30 cm in length and may contain, for example, 2 or 3 longitudinal slits 2624, or 2 or 3 helical slits (not shown), or a continuous helical slit (not shown). The slits 2620 in the expandable member may advantageously be between 5 mm and 20 mm in length, and the distal tip 2608 may advantageously be from 2 cm to 10 cm in length. The cuts in the distal tip 2608 may advantageously be from 0.002" to 0.030" wide. The last 2 cm or so of the device 2616 (the distal end) may include a gold wire or ribbon (not shown) to act as a radiopaque marker for the device.

As an alternative to the pull wire arrangement illustrated in **FIGURES 32** and **33**, the expandable member 2600 may be "shape set" so that the expandable member tends towards an expanded, deployed configuration in the absence of any applied external forces. In this case, the expandable member may be deployed using a sheath, in analogy with the embodiment of **FIGURE 30**. Also, in the embodiments of **FIGURES 32** and **33**, the distal tip may be optionally formed as a separate piece and joined to the hypotube 2612. In general, the distal tips disclosed herein preferably include radiopaque material (such as platinum or gold) to aid the practitioner in positioning the device within the vessel.

Those skilled in the art will recognize that the described embodiments are given as examples only, and that numerous variations which fall within the scope of the present invention may be appropriate in order to use the invention depending upon the circumstances under which it is used. The description of preferred embodiments above should not be deemed to limit the scope of the present invention.

WHAT IS CLAIMED IS:

1. An occlusion device, comprising:

an elongate tubular body having a proximal end and a distal end and a lumen extending therethrough;

a pull wire having a proximal end and a distal end extending through the lumen of the tubular body; and

a filter subassembly including a plurality of struts, said plurality of struts having a proximal end connected to the distal end of the elongate body and a distal end connected to the pull wire;

wherein the plurality of struts have a collapsed configuration and an expanded configuration, said collapsed configuration comprising the struts as they lie closest to the longitudinal axis of the elongate body and have the least radial extension, and said expanded configuration comprising the struts as they extend radially to their greatest extent from the longitudinal axis of the elongate body, said two configurations being selectable by displacement of the elongate body relative to the pull wire; and

wherein said plurality of struts are formed from a single piece of tubing.

2. The occlusion device of Claim 1, wherein said single piece of tubing is made from nitinol.

3. The occlusion device of Claim 1, wherein said plurality of struts are formed by forming longitudinal slits in said single piece of tubing.

4. The occlusion device of Claim 1, wherein said plurality of struts are formed by forming slits in said single piece of tubing.

5. The occlusion device of Claim 4, wherein said slits are helically formed.

6. The occlusion device of Claim 4, wherein said slits are longitudinally formed.

7. The occlusion device of Claim 1, wherein the struts are formed by laser cutting the single piece of tubing.

8. The occlusion device of Claim 1, wherein the struts are formed by EDM cutting of the single piece of tubing.

9. The occlusion device of Claim 1, wherein the filter subassembly is separately attached to the elongate tubular body.

10. The occlusion device of Claim 1, wherein the single piece of tubing includes a plurality of helical cuts proximal to said plurality of struts.

11. The occlusion device of Claim 10, wherein the single piece of tubing includes a plurality of helical cuts distal to said plurality of struts.

12. The occlusion device of Claim 11, wherein the pitch of the spiral cuts distal to the struts is smaller than that of the spiral cuts proximal to the struts.

13. The occlusion device of Claim 1, further comprising a porous membrane attached along at least a distal portion of the filter subassembly.

14. The occlusion device of Claim 1, wherein one or more of the struts includes a flattened hinge region which bends more easily than the remainder of the strut.

15. The occlusion device Claim 1, further comprising a plurality of holes disposed in the elongate tubular body, said holes passing into the lumen of said tubular body, and said holes located near the distal end of the tubular body, but proximal of the set of struts.

16. The occlusion device Claim 1, further comprising an additional set of struts, disposed distally of the first set of struts, said additional set of struts having at least two configurations, a collapsed configuration and an expanded configuration.

17. The occlusion device Claim 16, wherein said additional set of struts is adjustable between the collapsed and expanded configuration independent of the adjustment of the other set of struts.

18. The occlusion device Claim 17, wherein said additional set of struts supports an additional filter membrane.

19. The occlusion device Claim 1, wherein said two configurations are selectable by longitudinal displacement of the elongate body relative to the pull wire.

20. The occlusion device Claim 1, wherein said two configurations are selectable by rotational displacement of the elongate body relative to the pull wire.

21. The occlusion device Claim 1, wherein said single piece of tubing includes between 4 and 16 struts.

22. The occlusion device Claim 21, wherein said single piece of tubing includes between 6 and 12 struts.

23. A filter device, comprising:

an elongate tubular body having a proximal end and a distal end and a lumen extending therethrough;

a section of the tubular body near its distal end that receives a plurality of longitudinal cuts to form struts therein; and

a section proximal to the struts wherein the tubular body receives spiral cuts.

24. The filter device of Claim 23, further comprising a section distal to the struts receiving spiral cuts.

25. The filter device of Claim 24, wherein the pitch of the spiral cuts distal to the struts is smaller than that of the spiral cuts proximal to the struts.

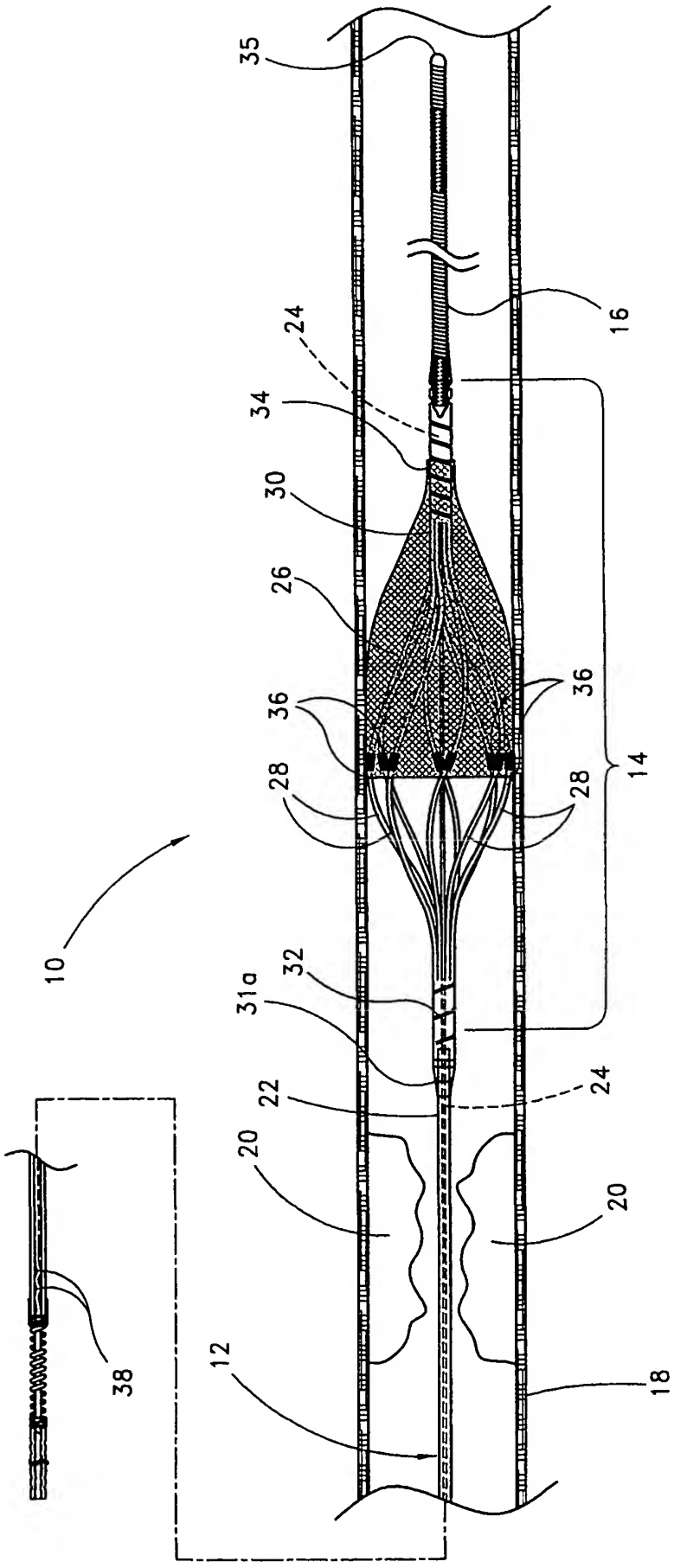


Fig. 1

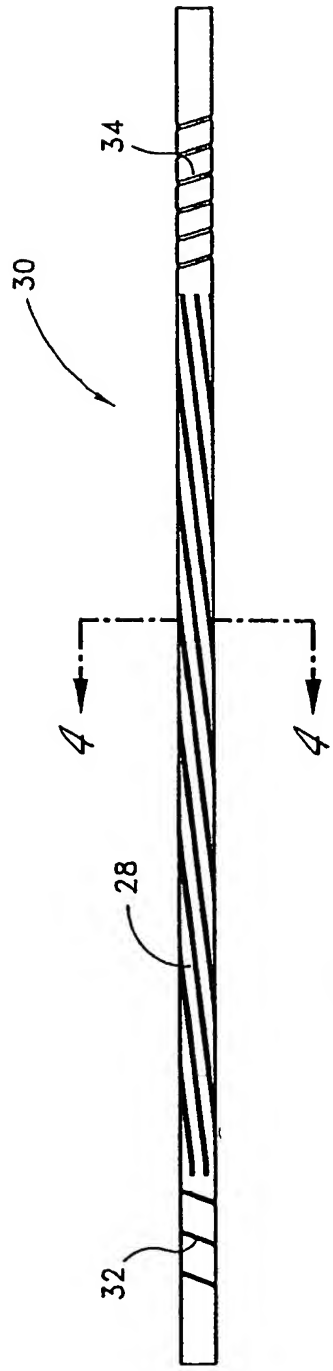


Fig. 2

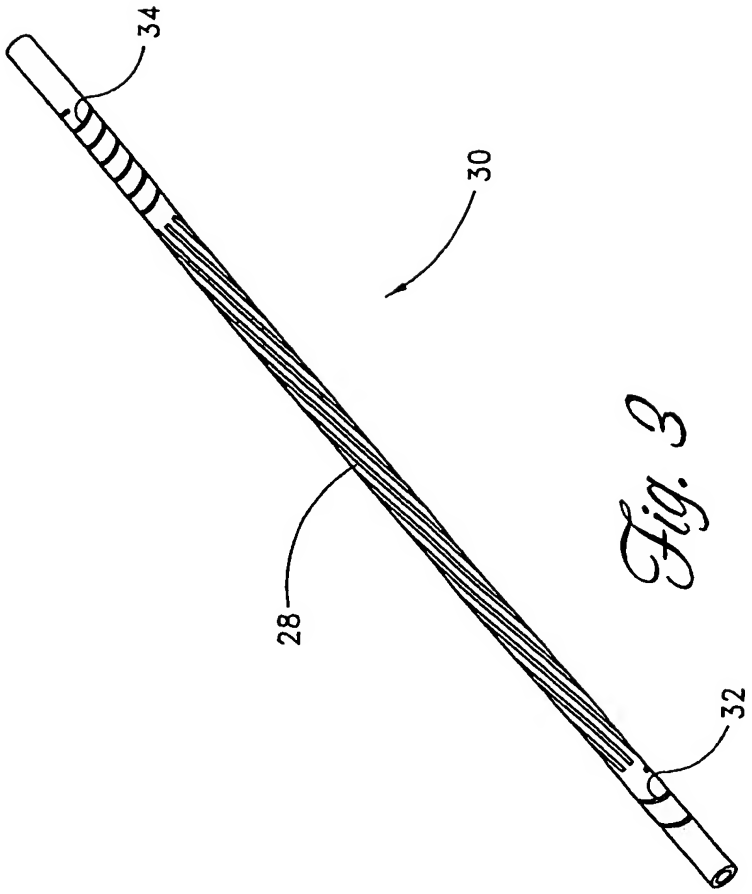


Fig. 3

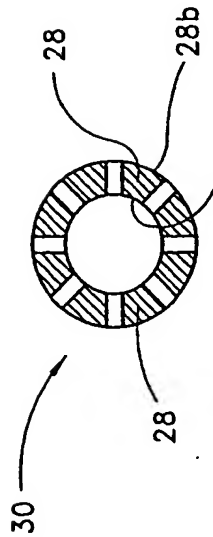


Fig. 4

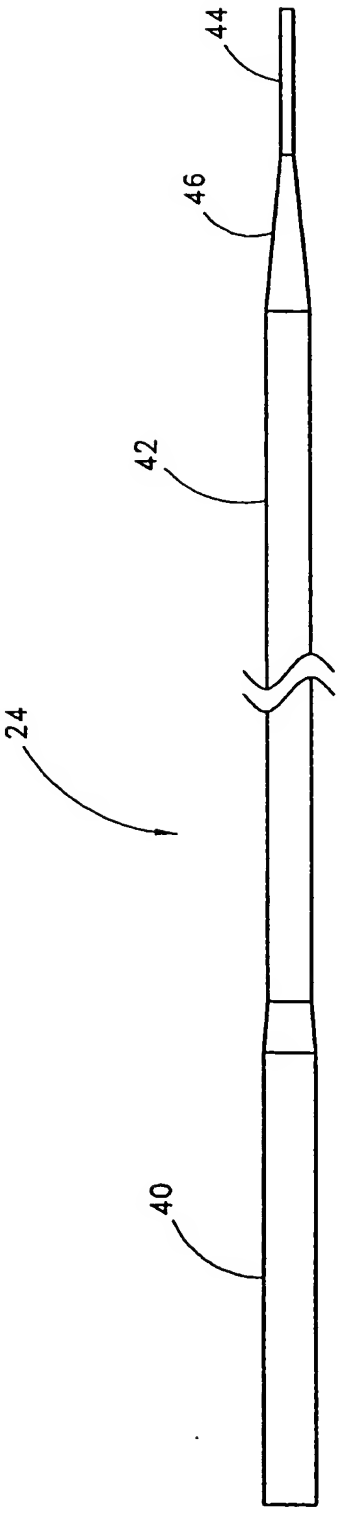


Fig. 5

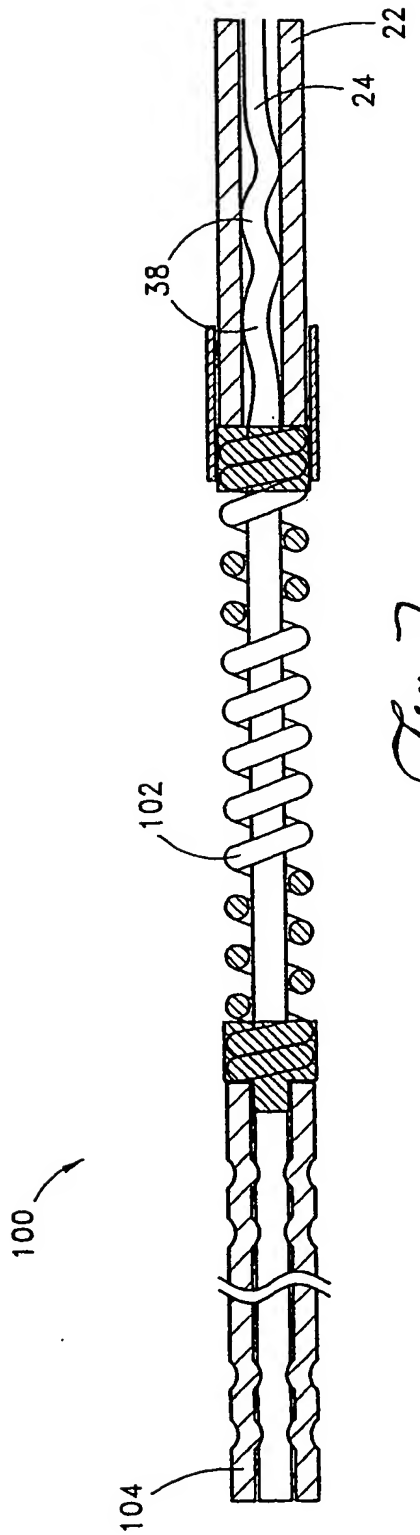


Fig. 7

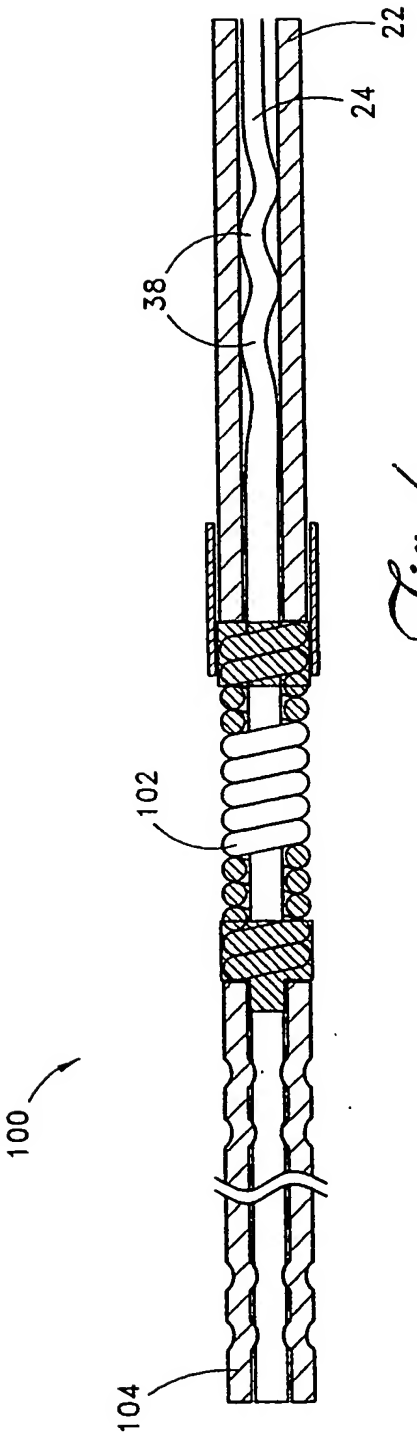
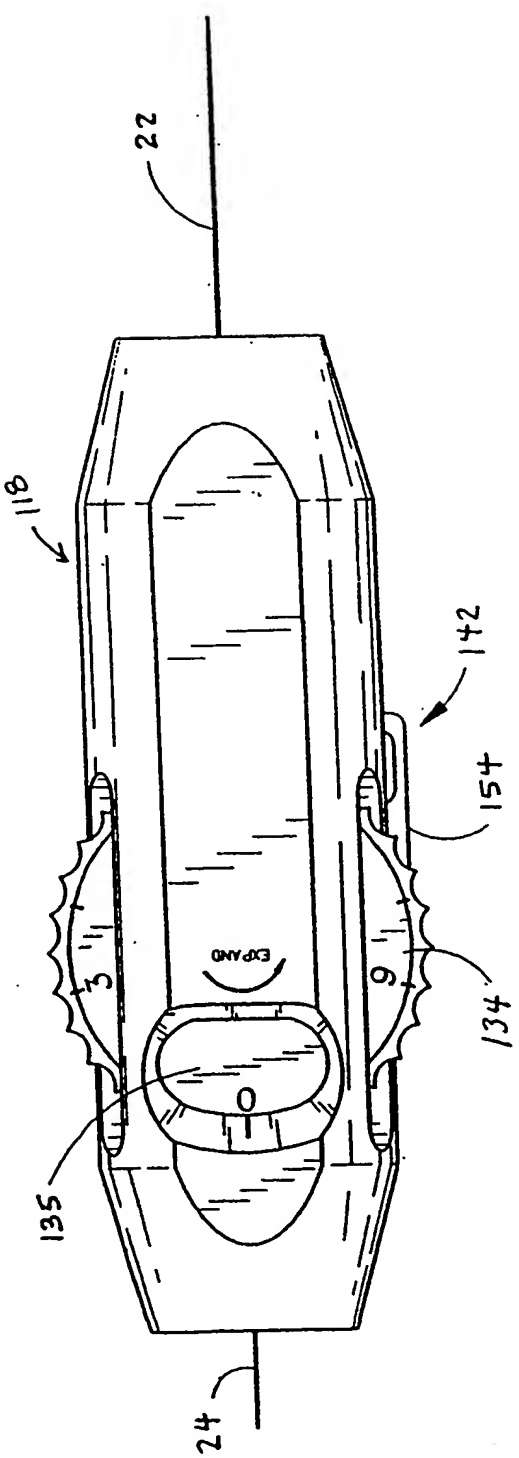


Fig. 6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134
135
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9
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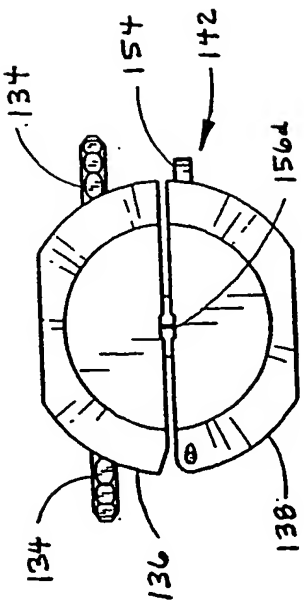
FIG. 8A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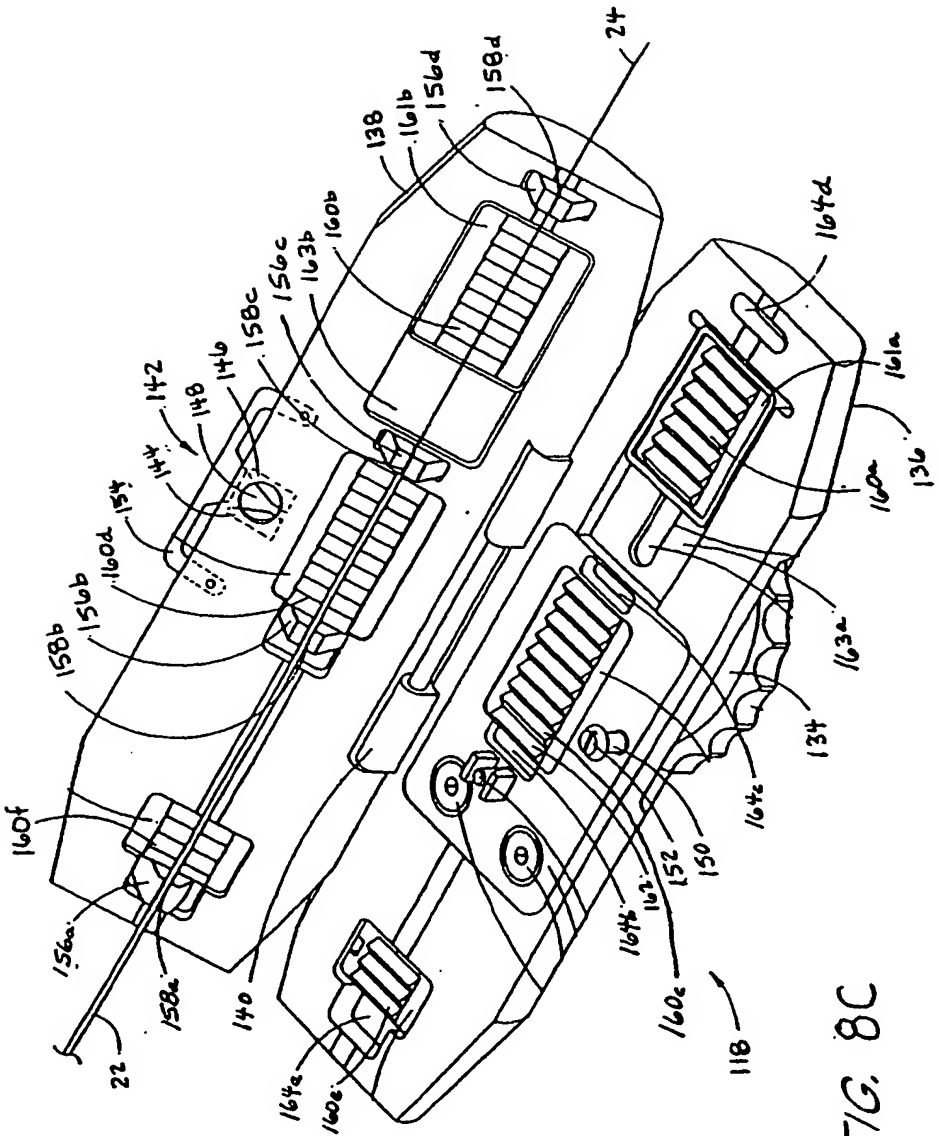
134
136
138

FIG. 8B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160f
156a
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164c
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161a
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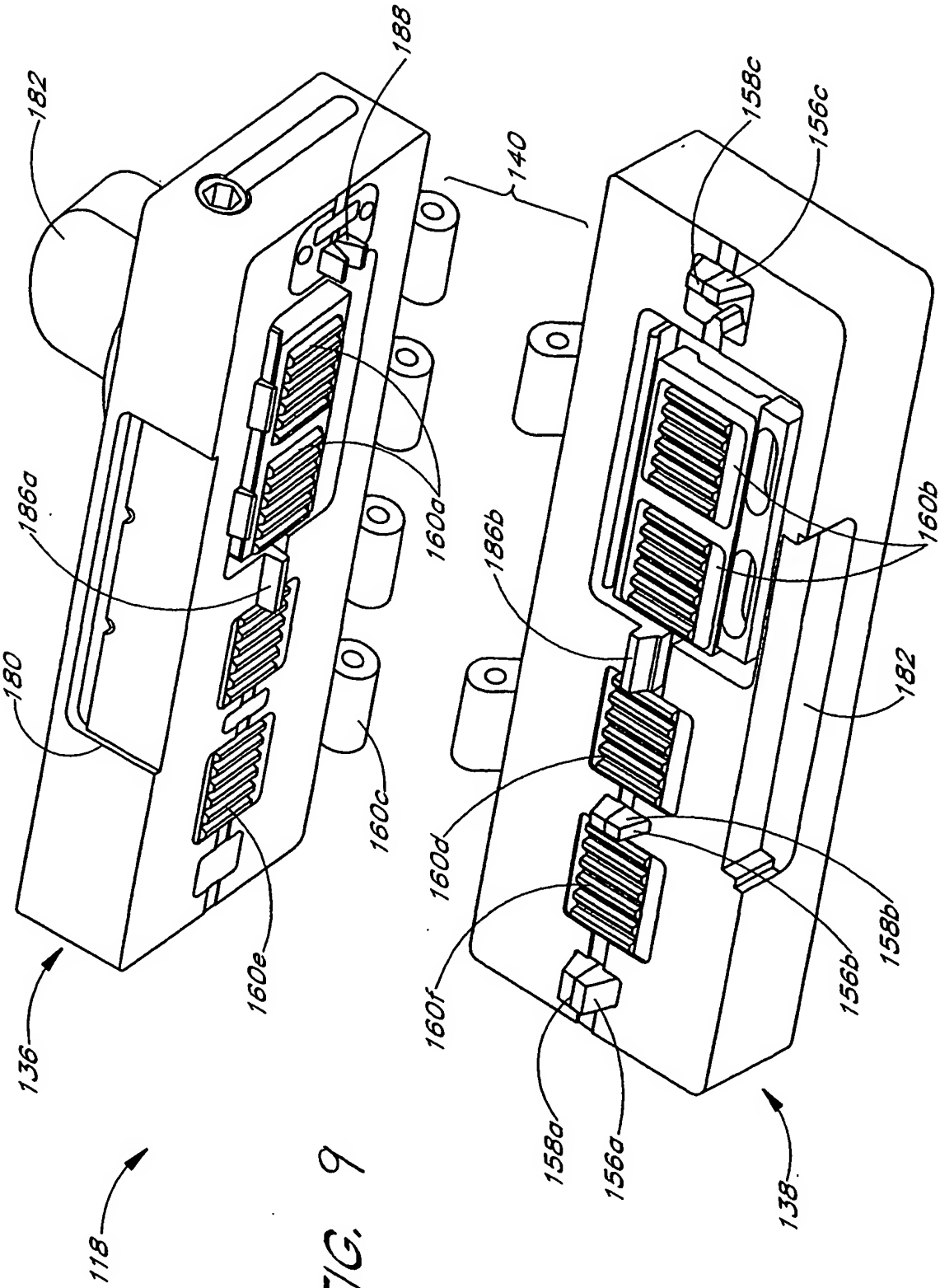
164d

FIG. 8C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158a
156a
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FIG. 9

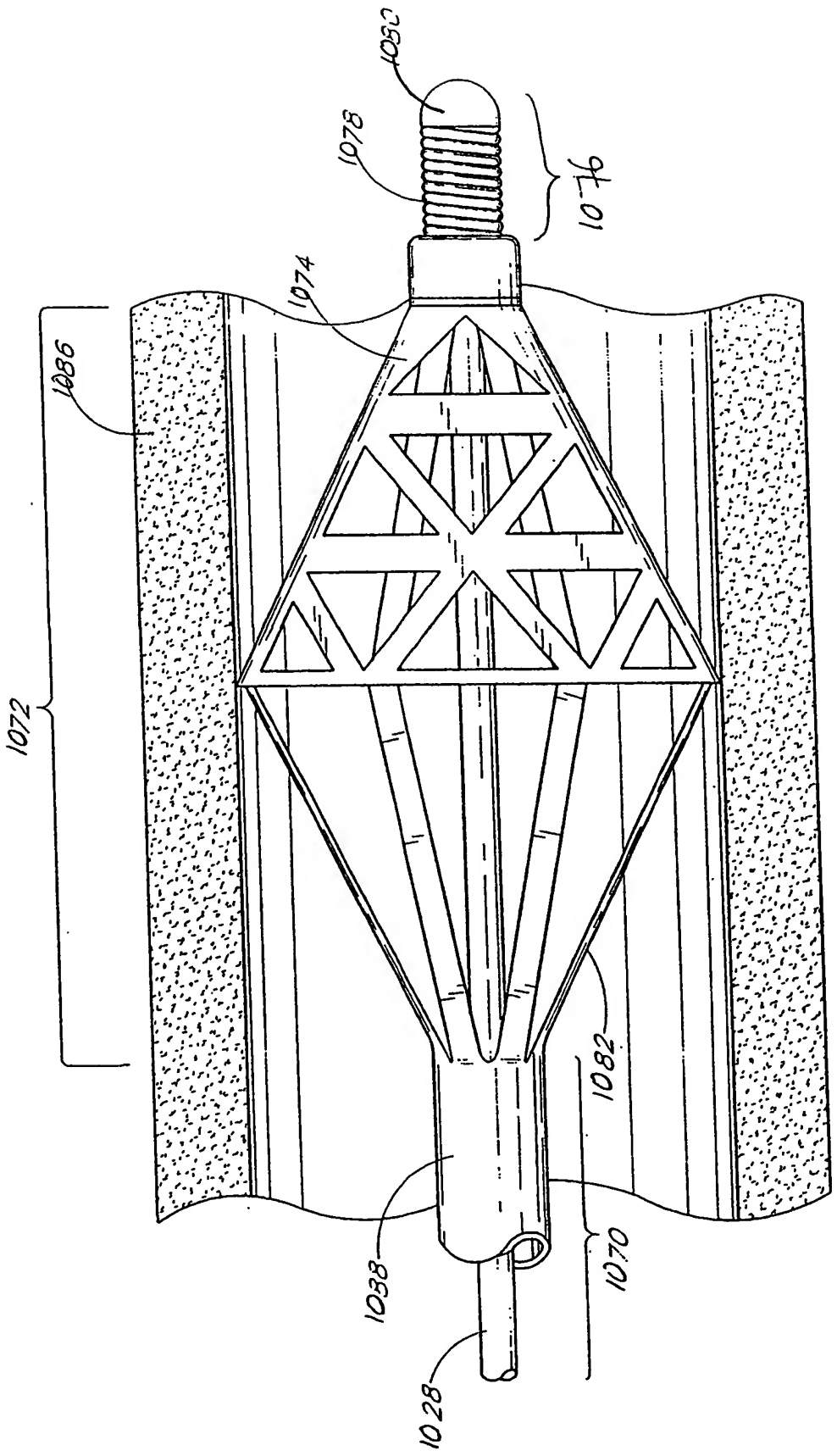


FIG. 10

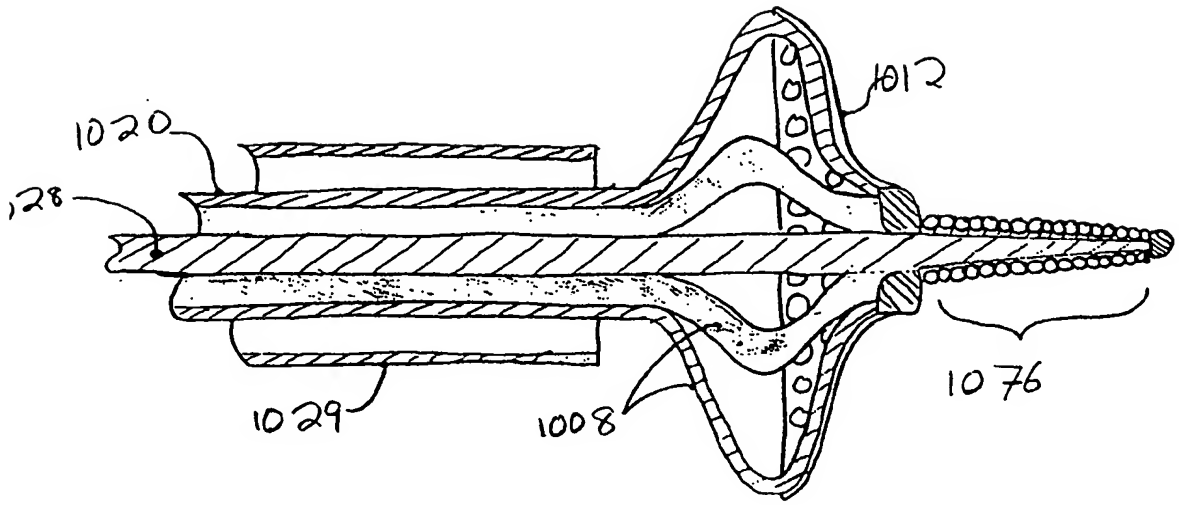


FIGURE 11A

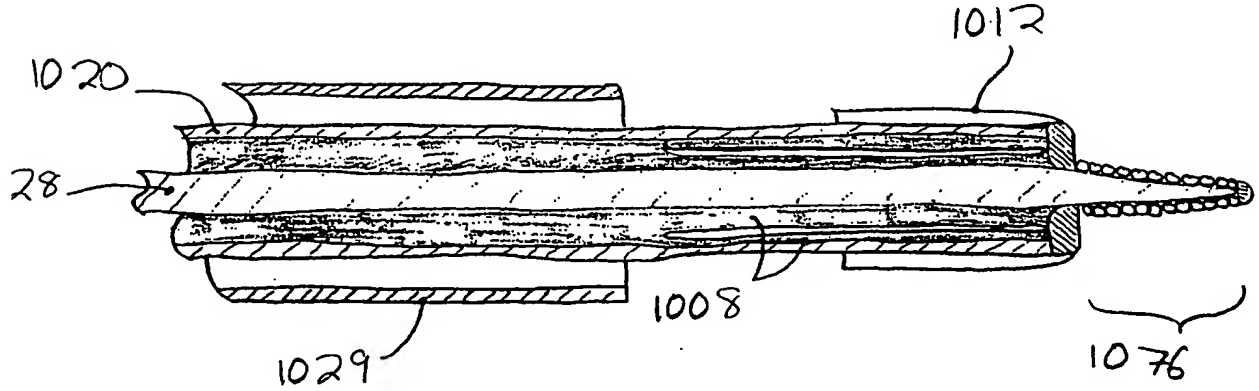


FIGURE 11B

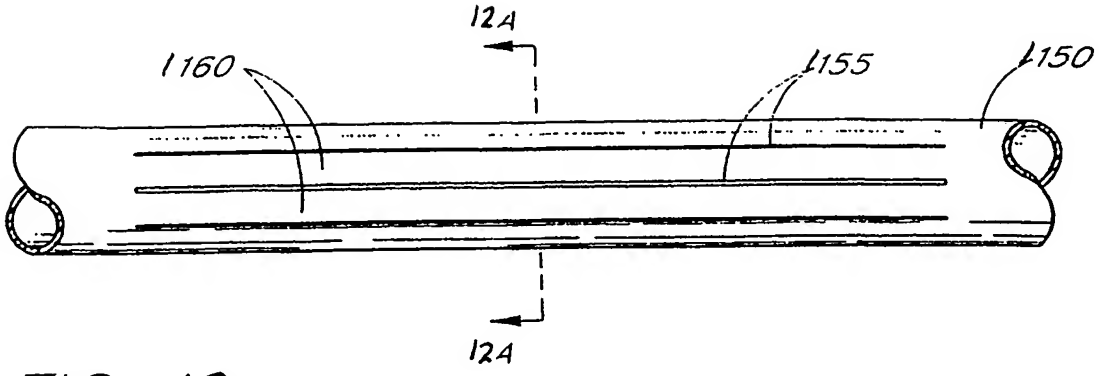


FIG. 12

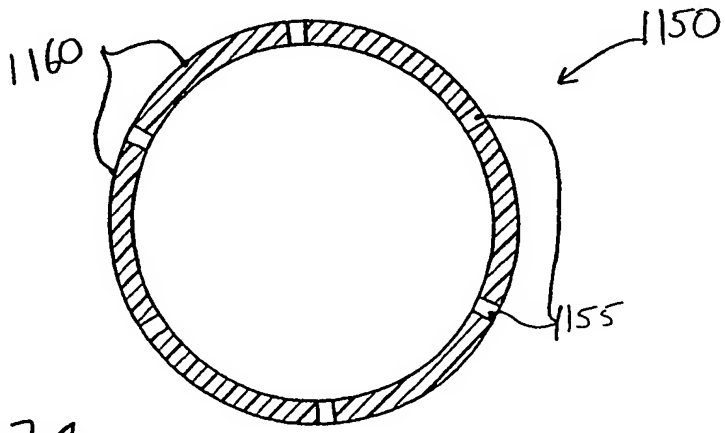


FIG. 12A

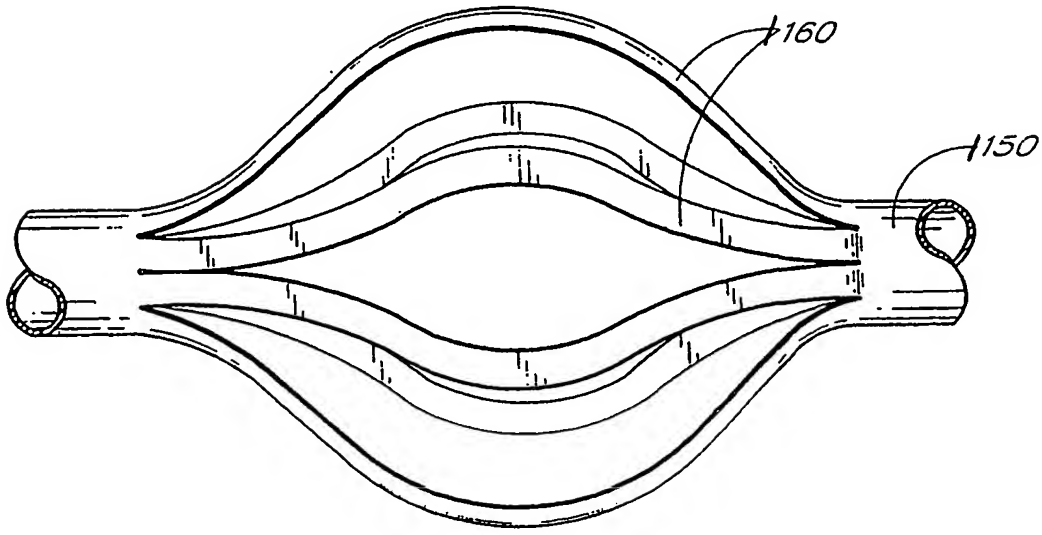


FIG. 13

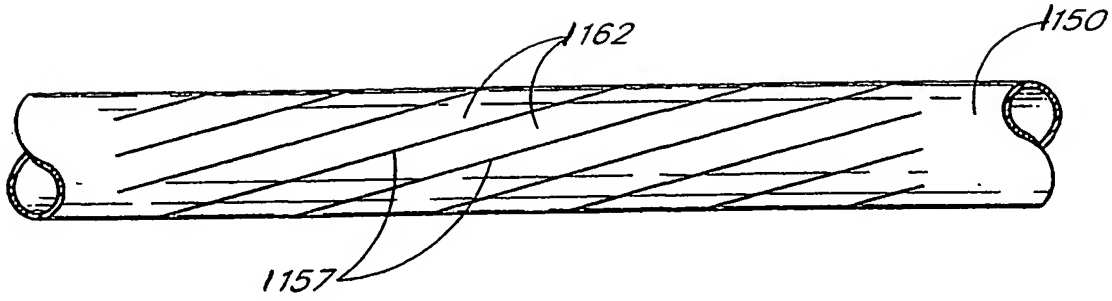
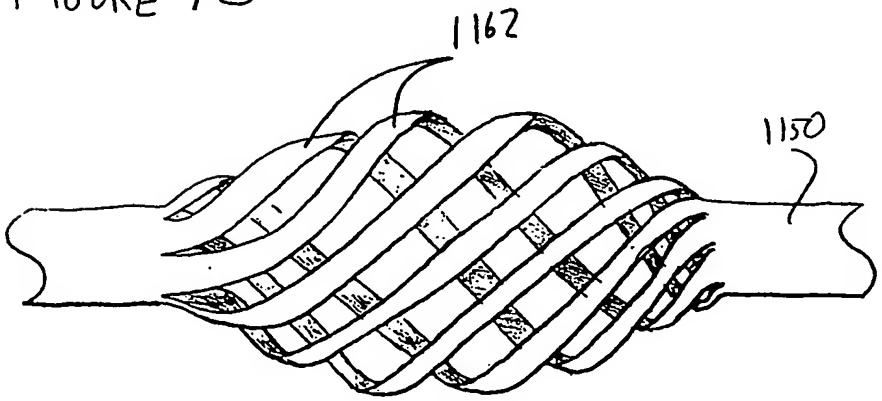


FIG. 14

FIGURE 15



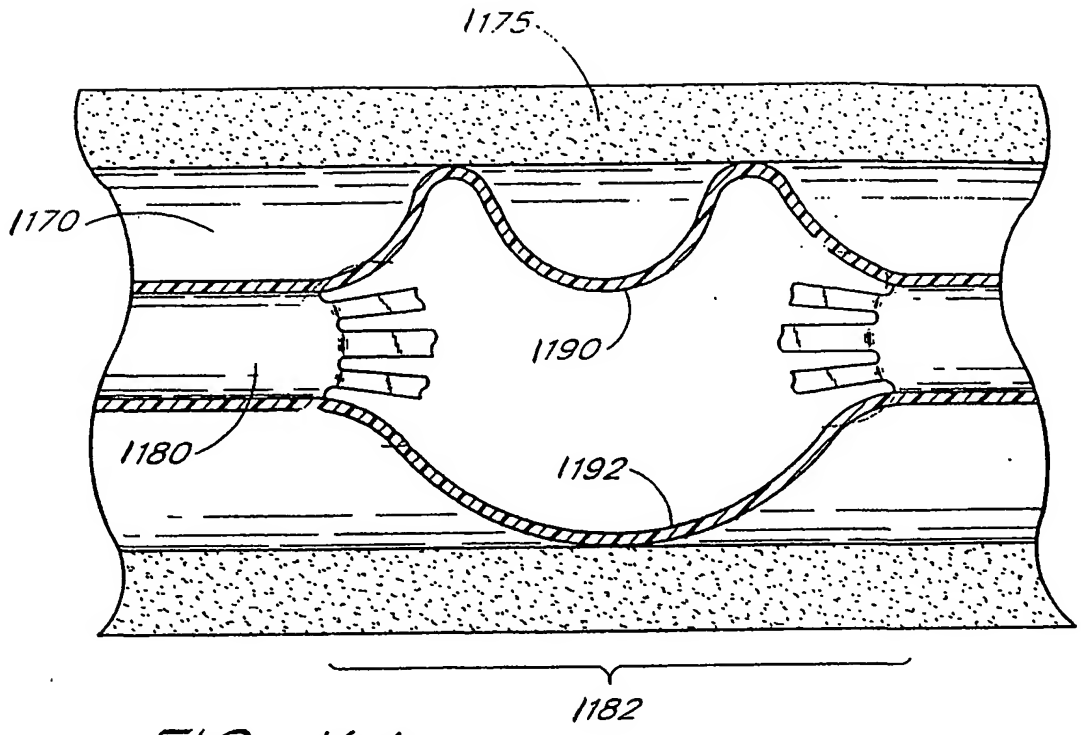


FIG. 16A

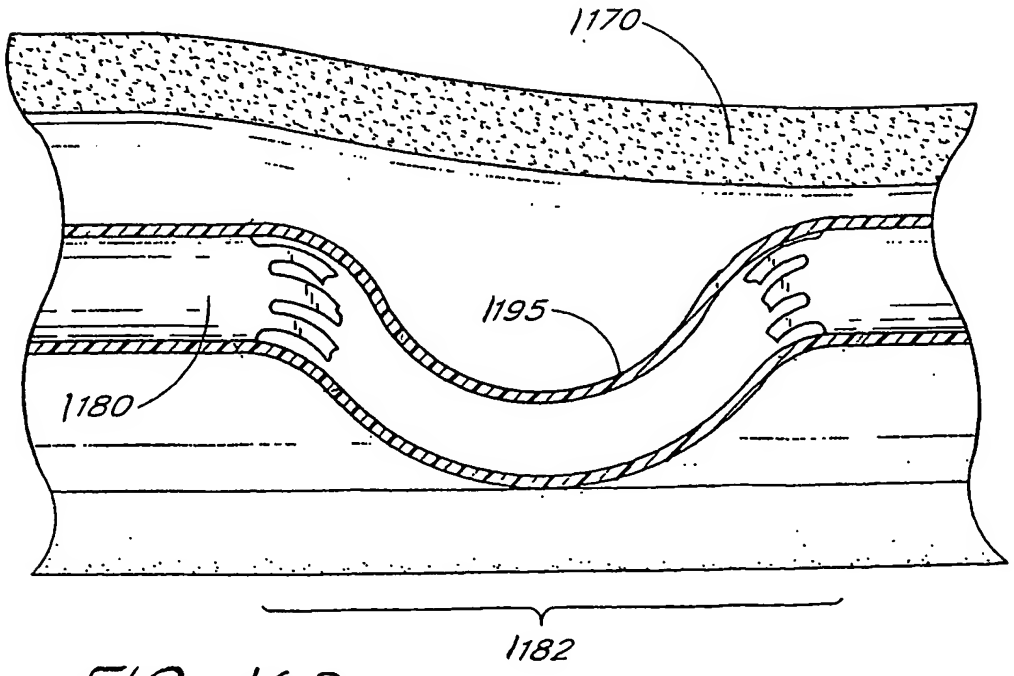


FIG. 16B

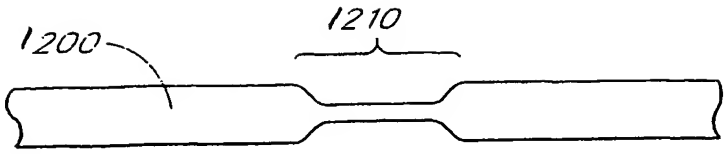


FIG. 17A

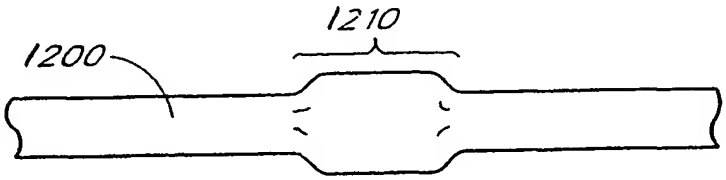


FIG. 17B

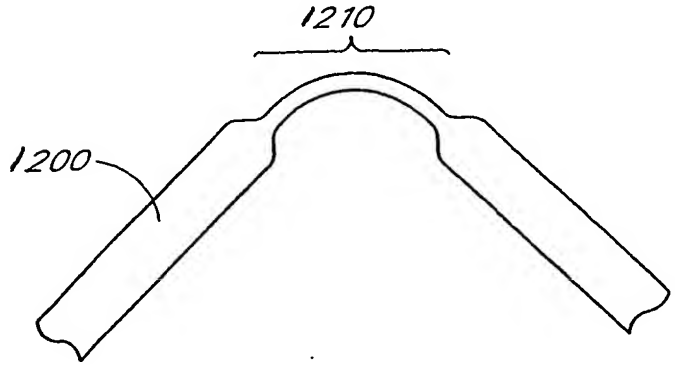


FIG. 18A

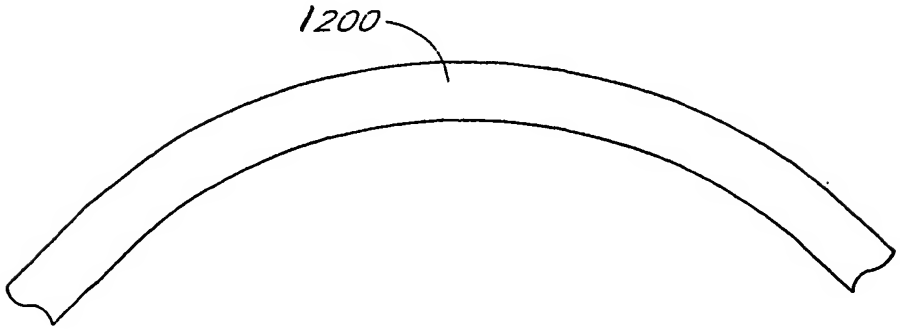


FIG. 18B

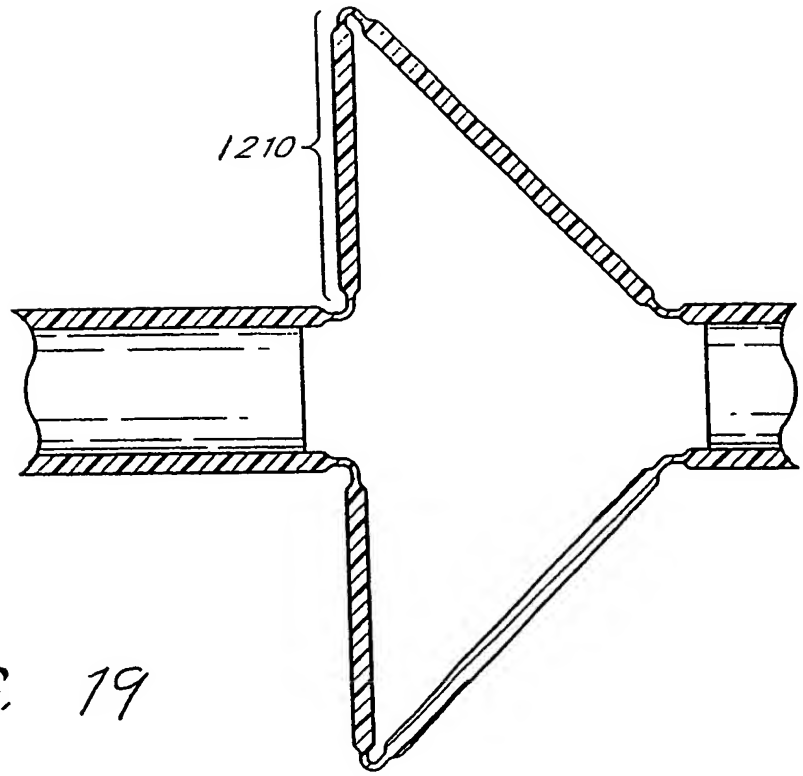


FIG. 19

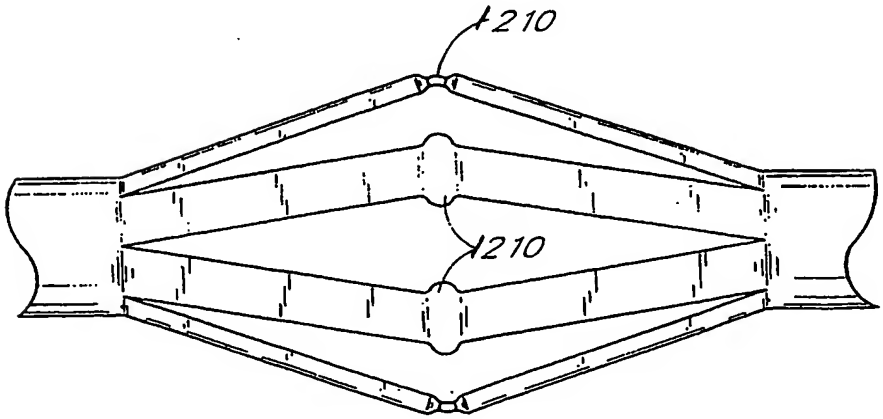


FIG. 20

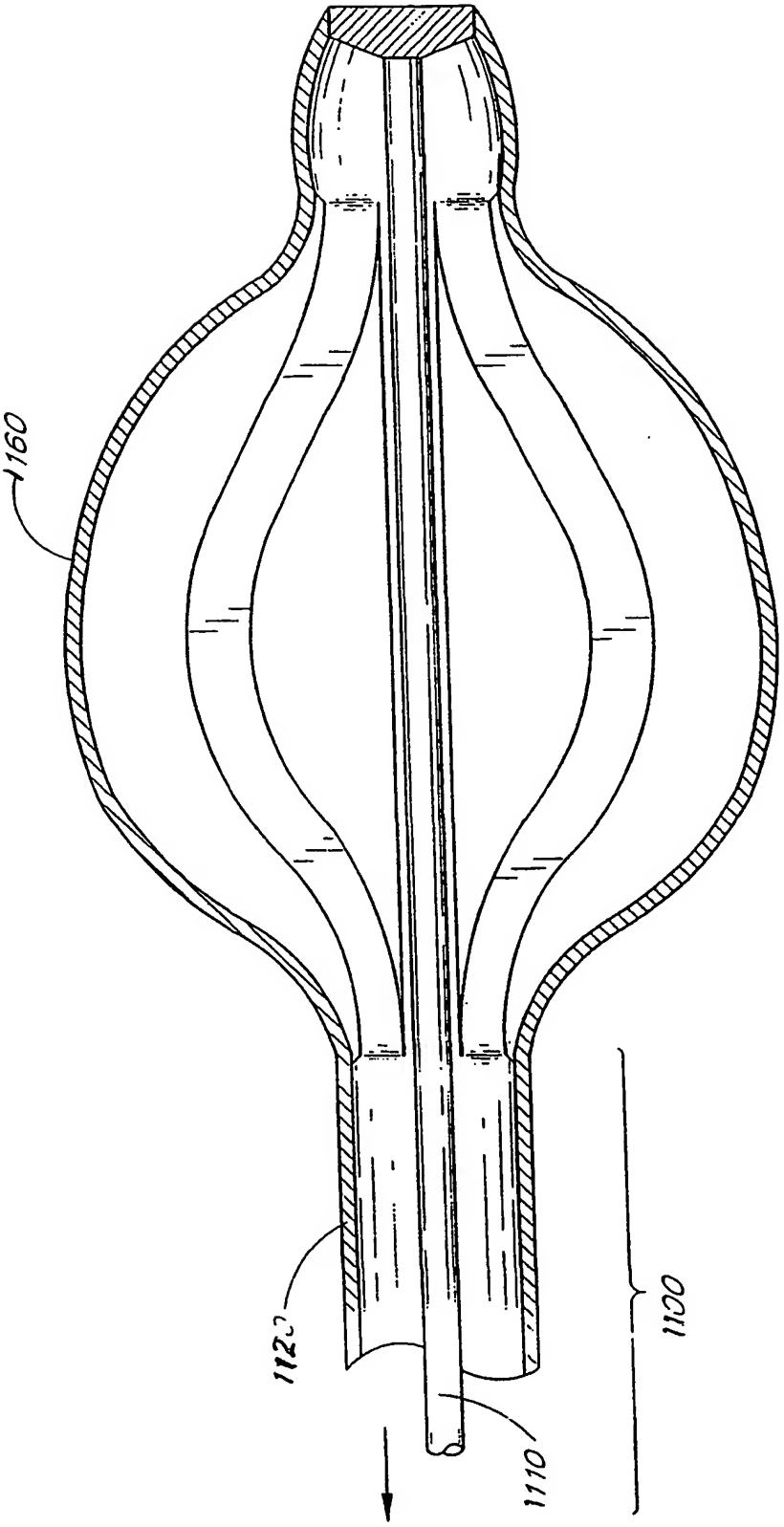


FIG. 21

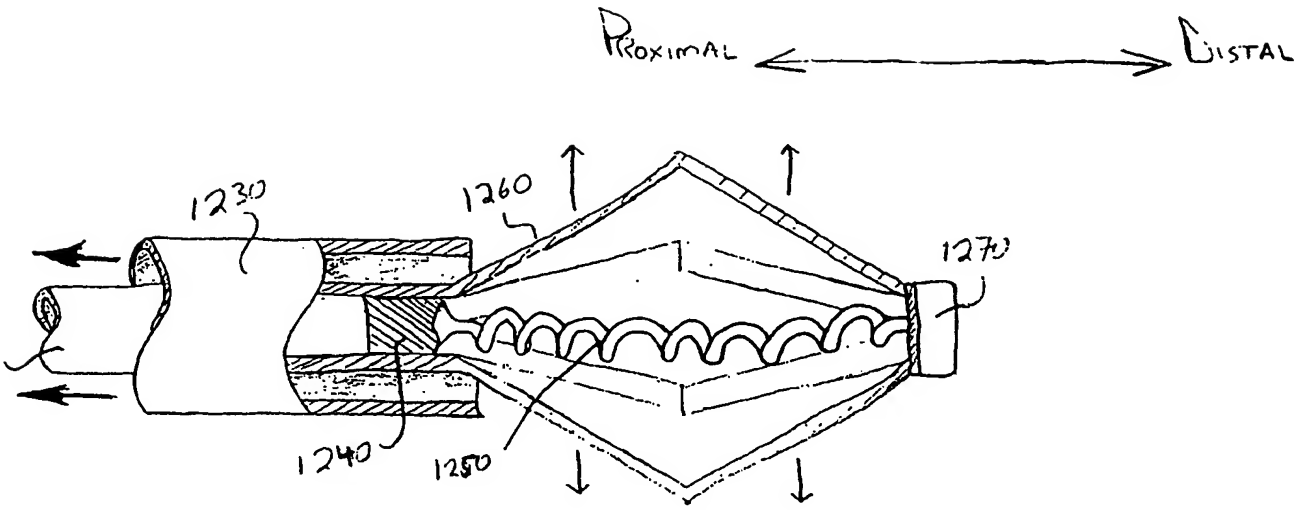


FIGURE 21A

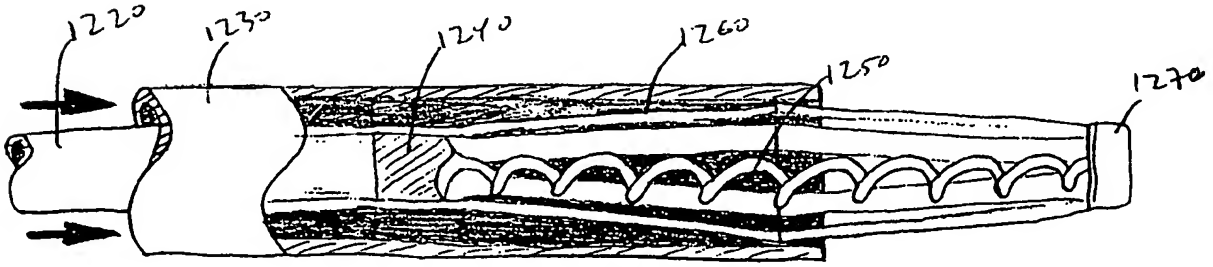


FIGURE 21B

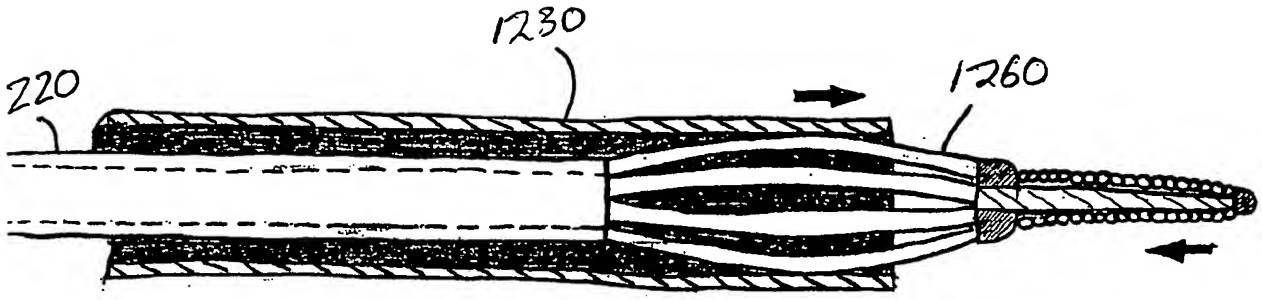


FIGURE 21C

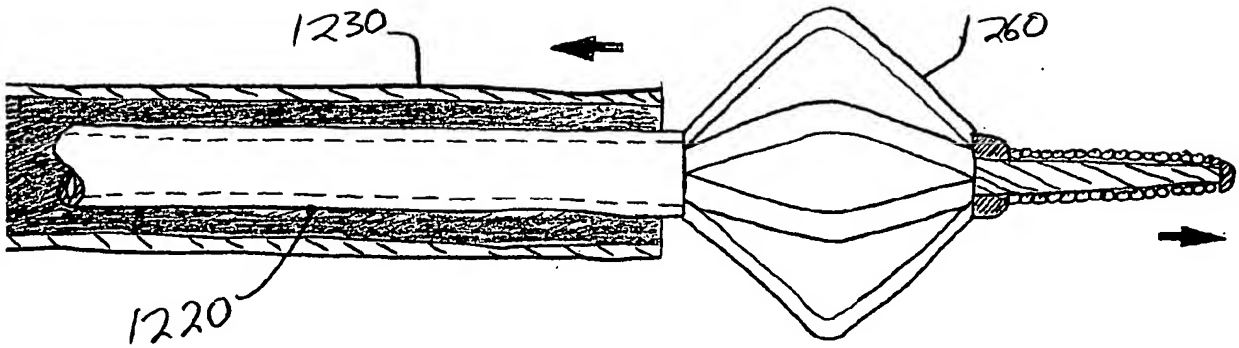


FIGURE 21D

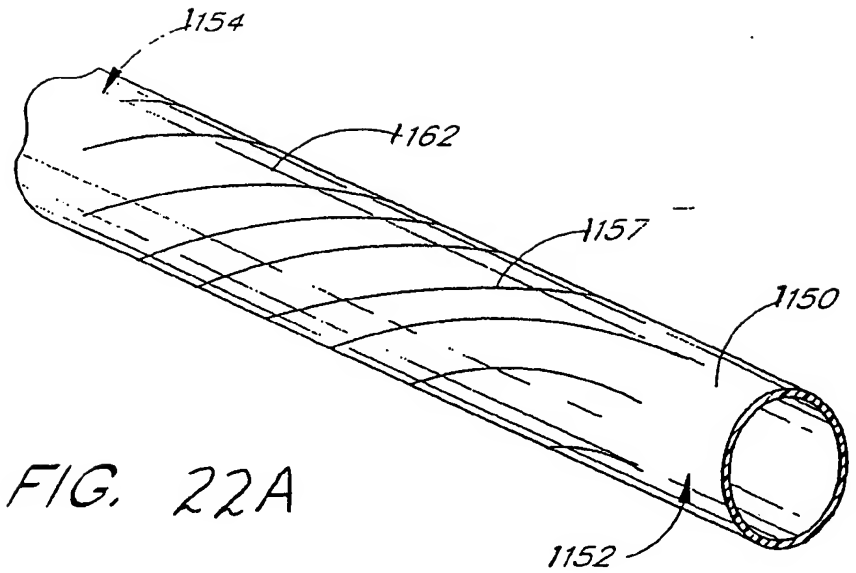


FIG. 22A

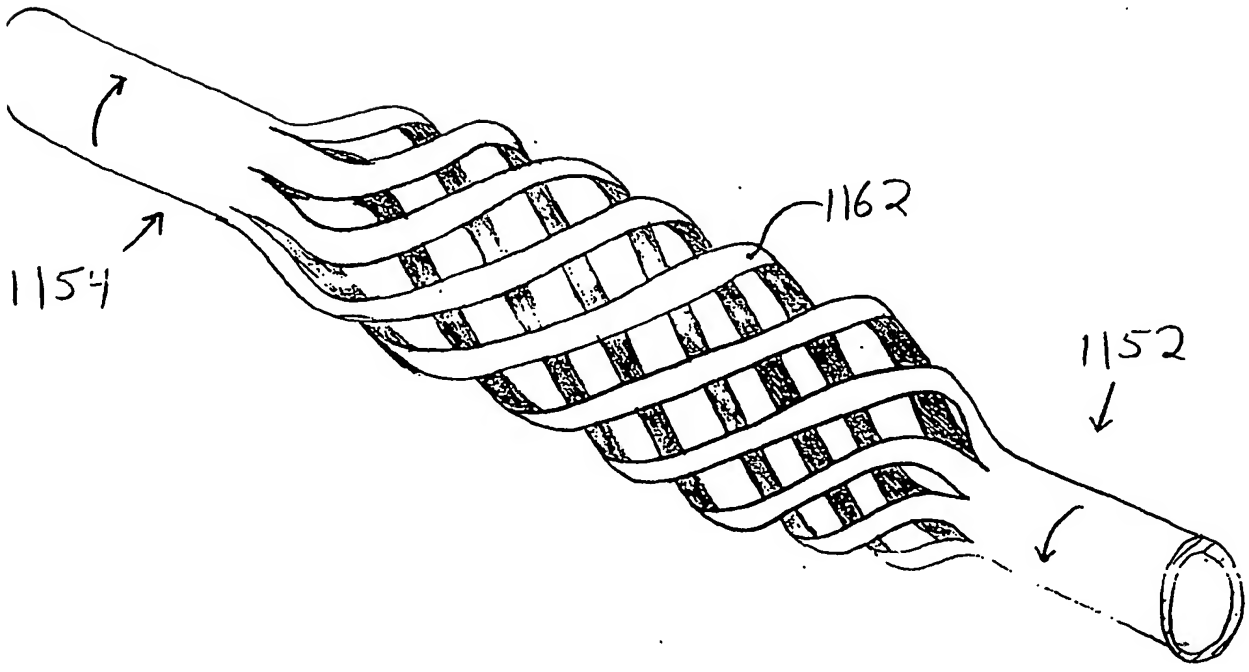


FIGURE 22B

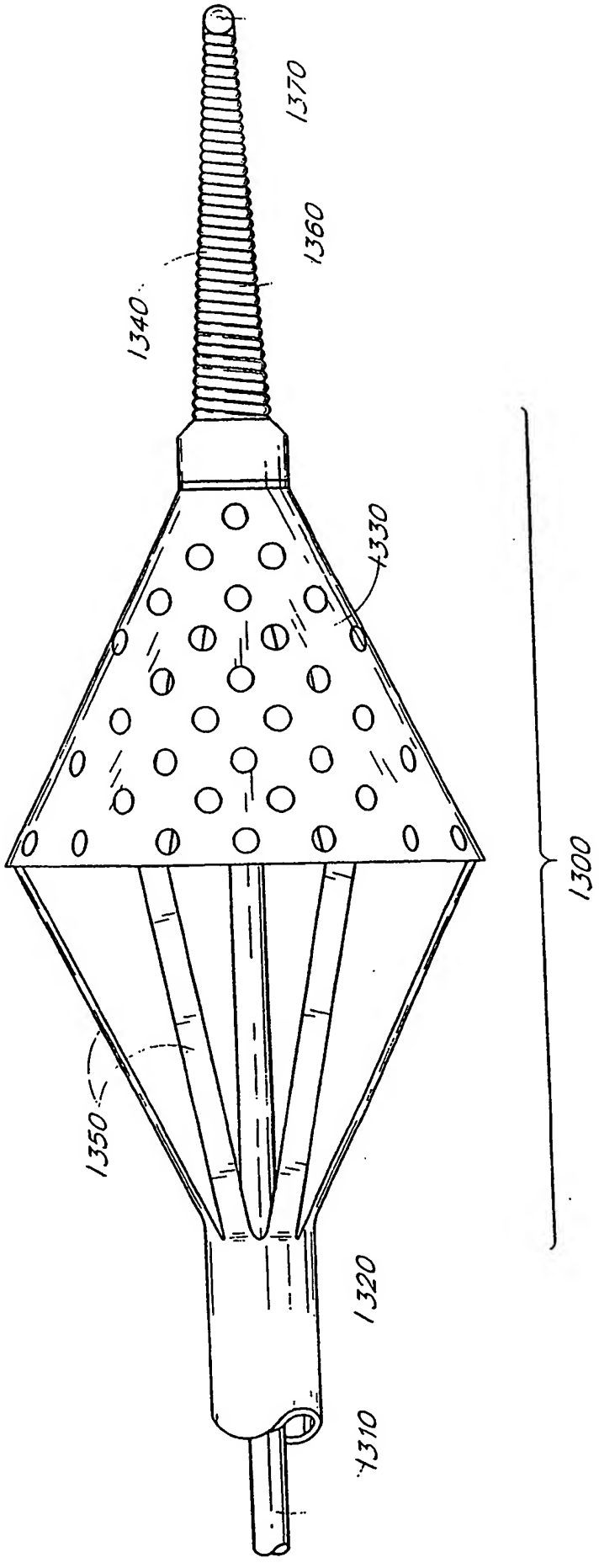


FIG. 23

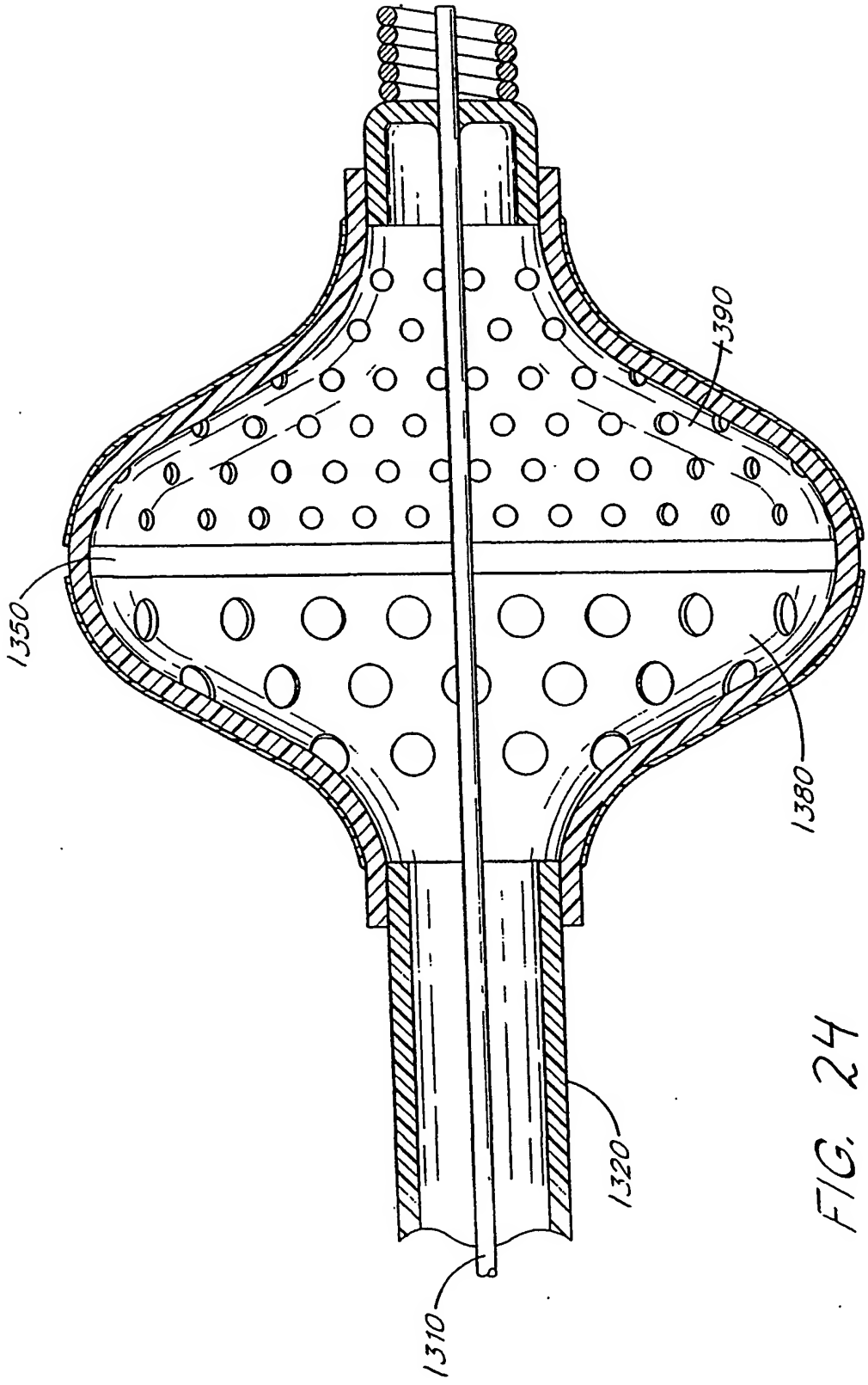


FIG. 24

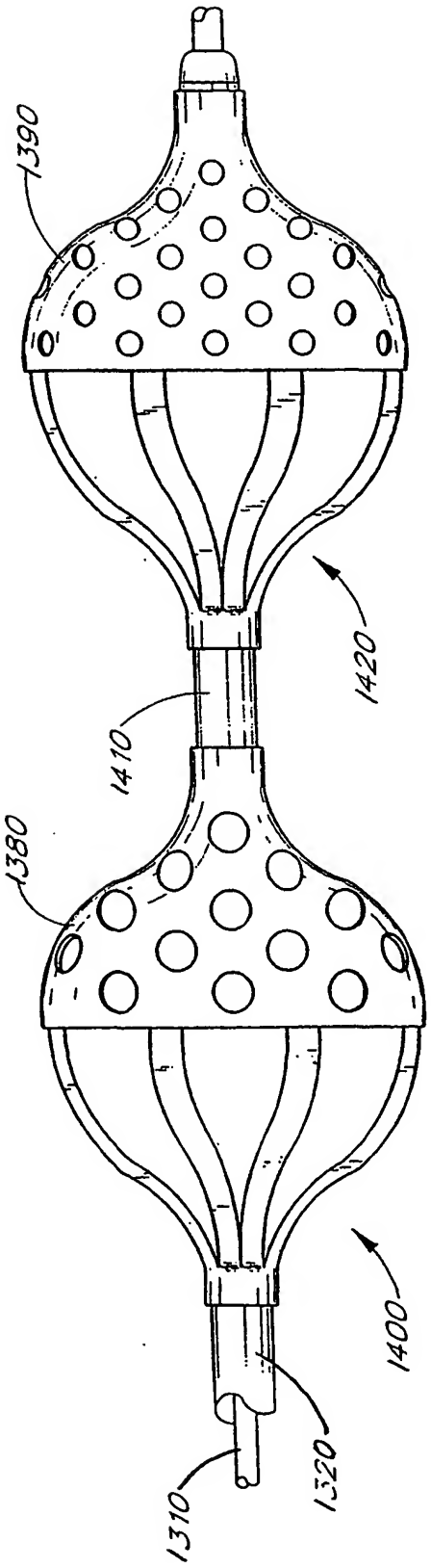


FIG. 25

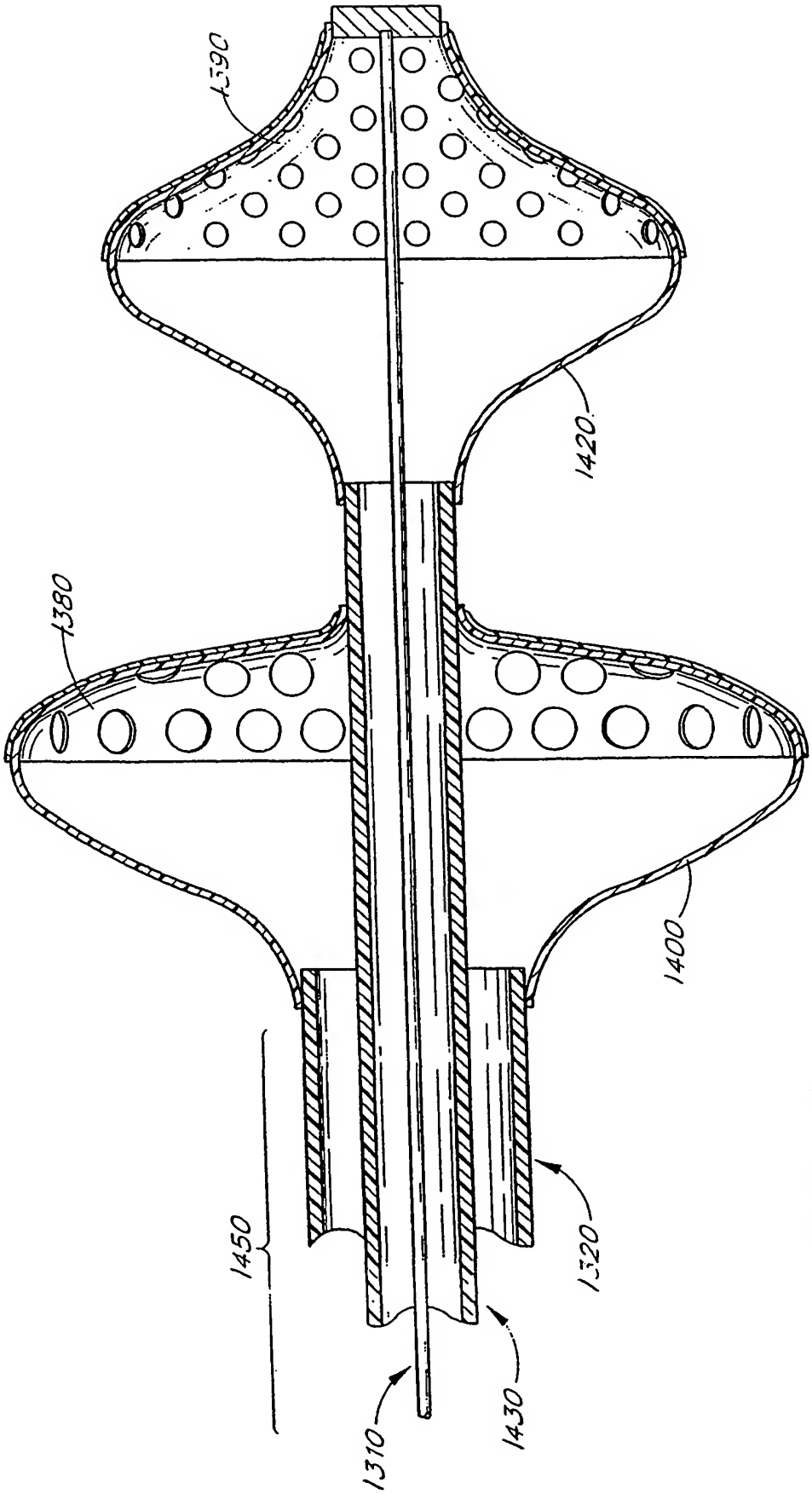


FIG. 26

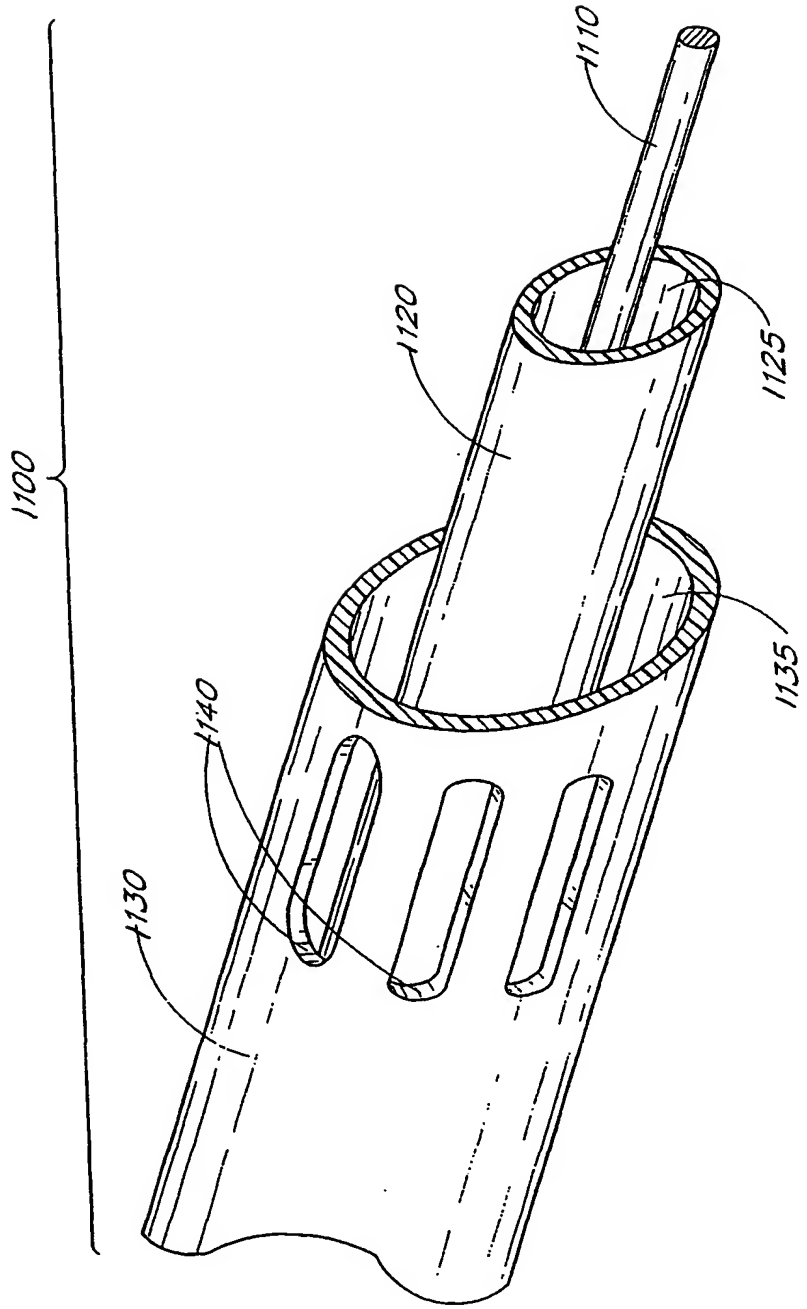


FIG. 26A

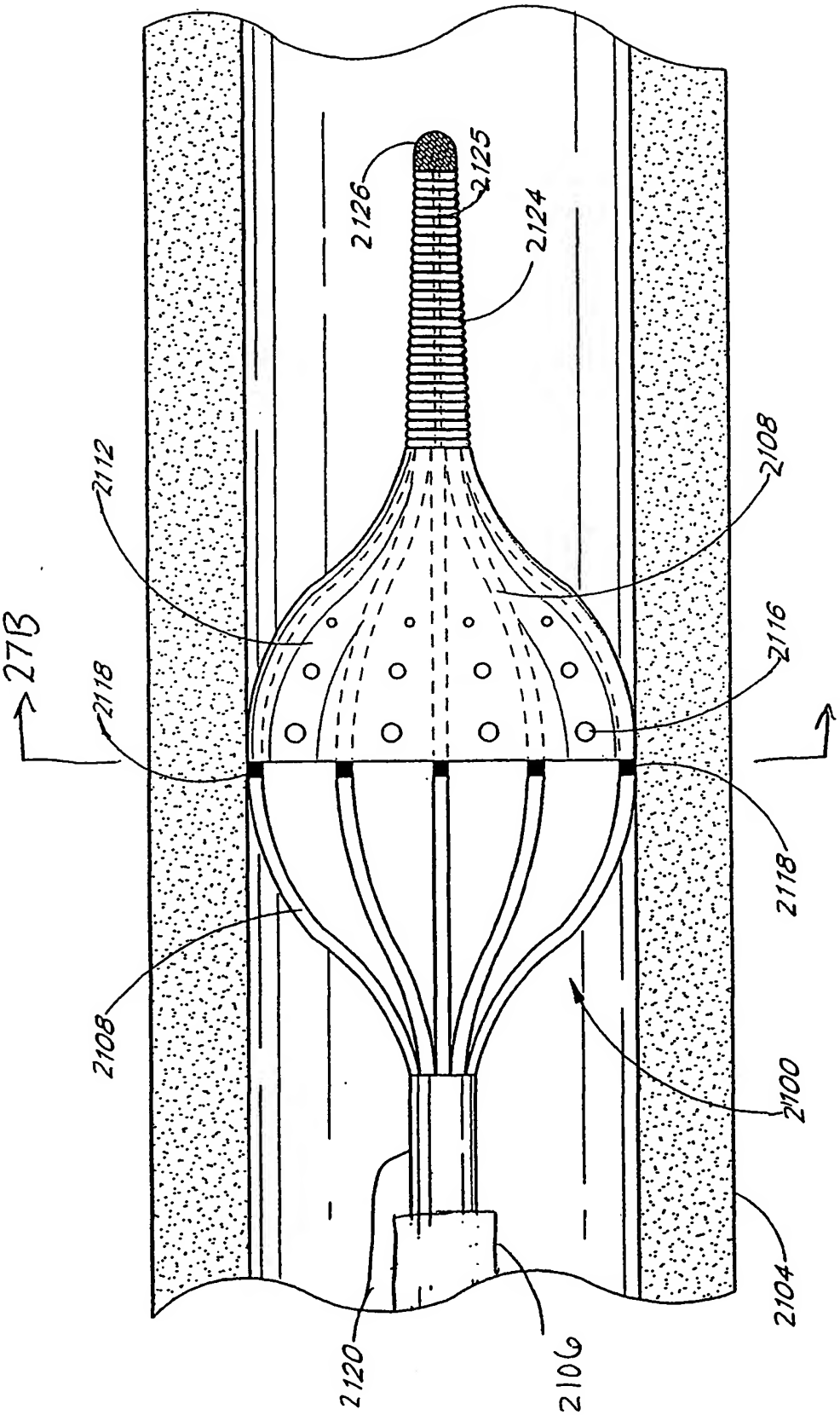

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FIG. 27A

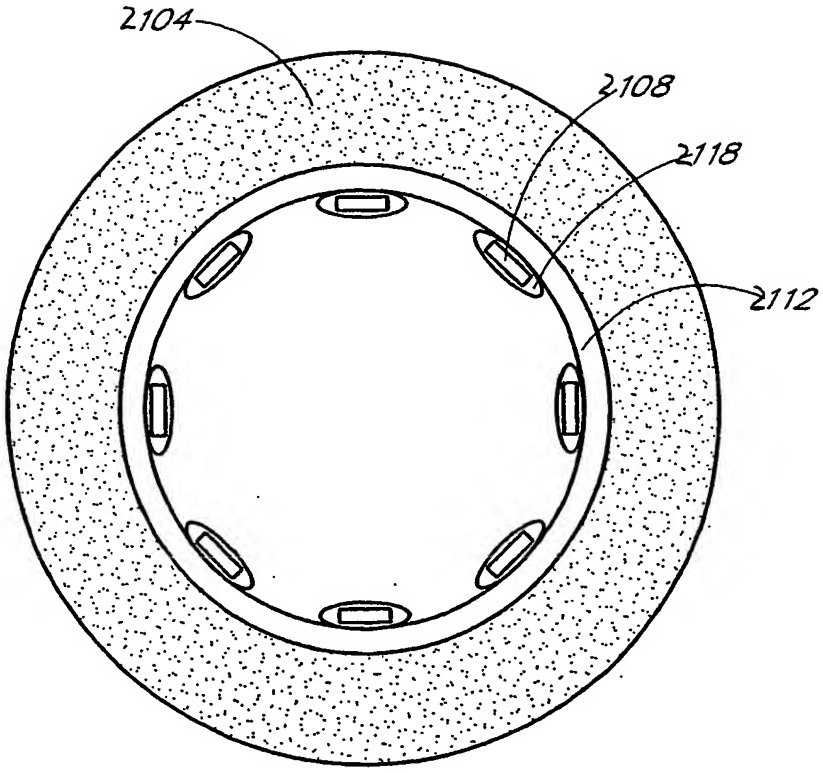

FIG. 27B

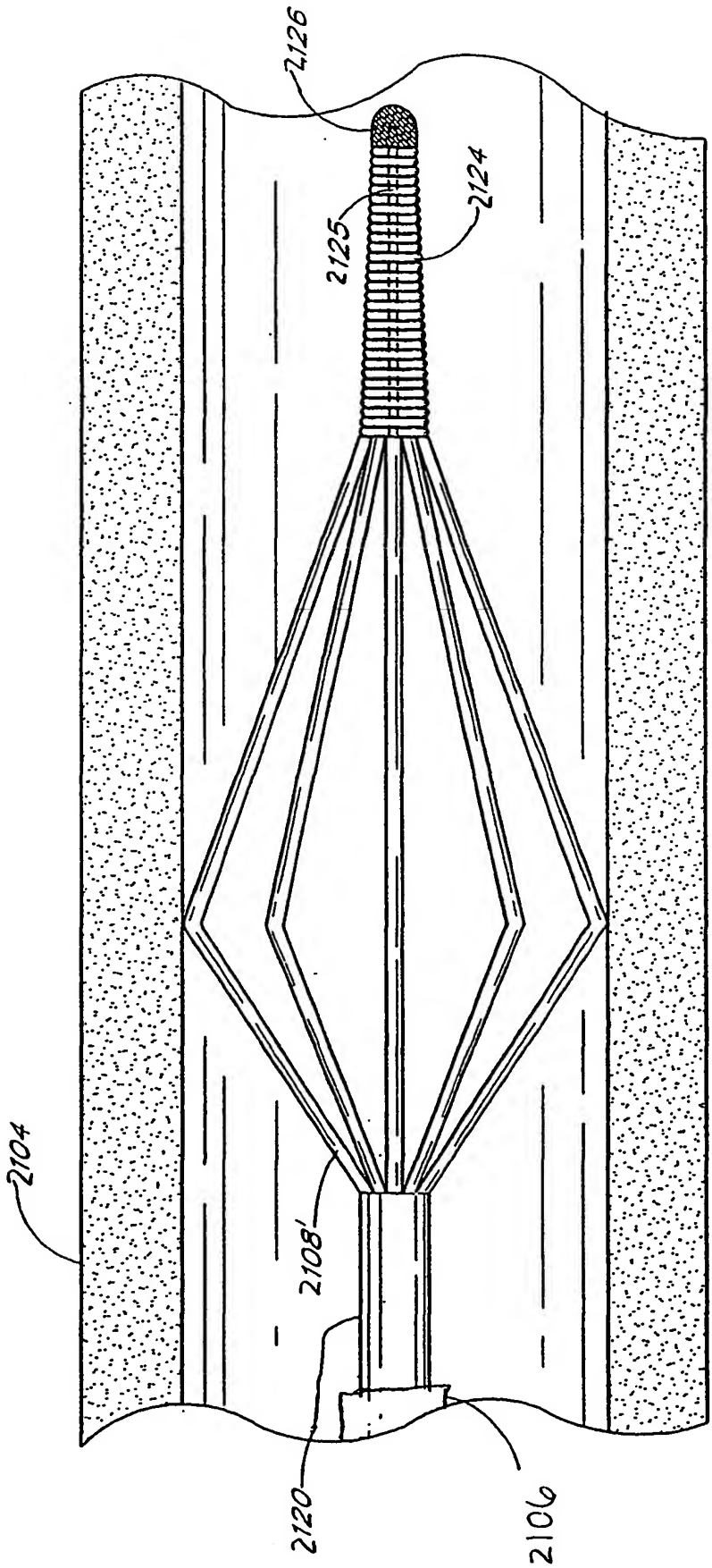

FIG. 27C

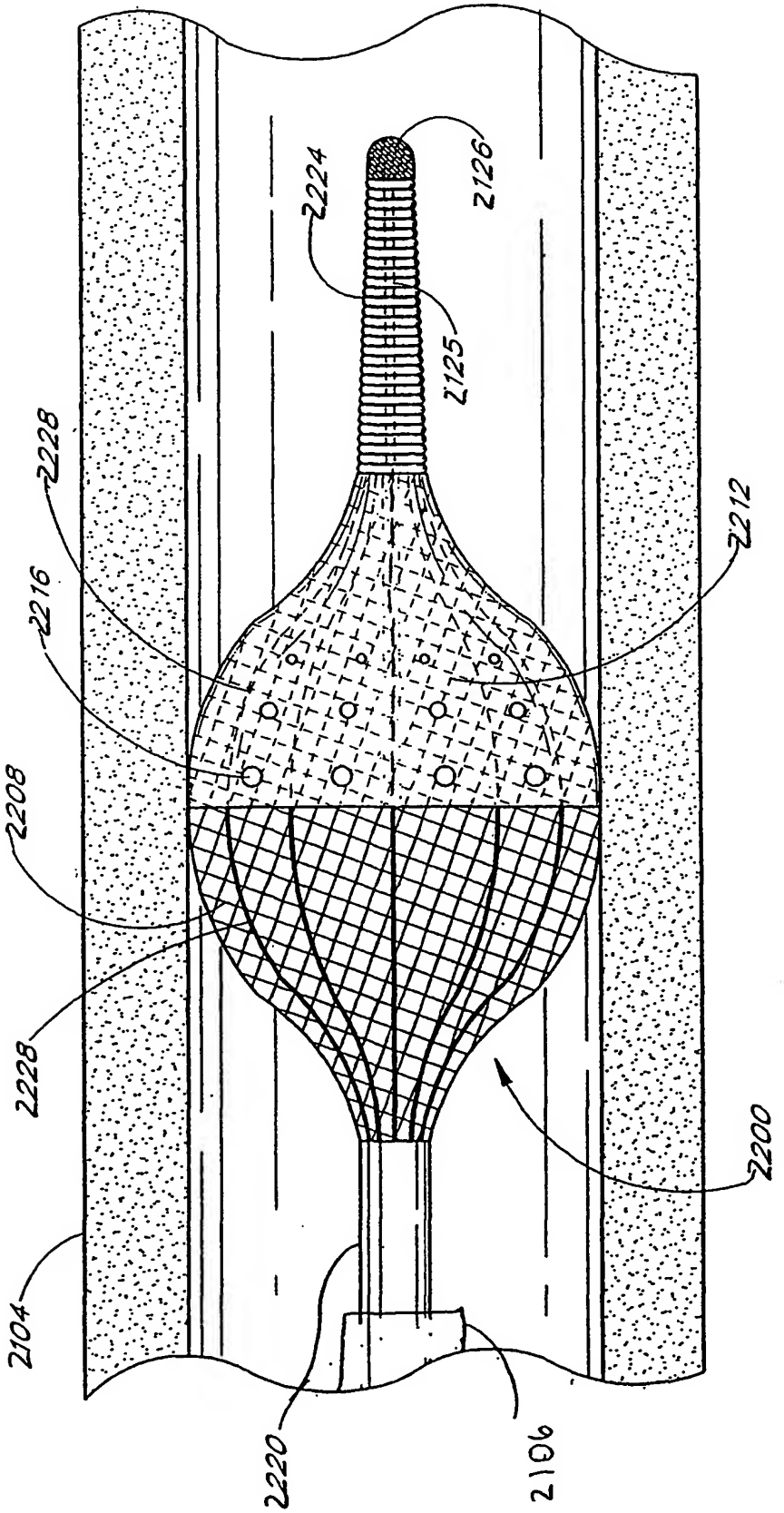

FIG. 28A

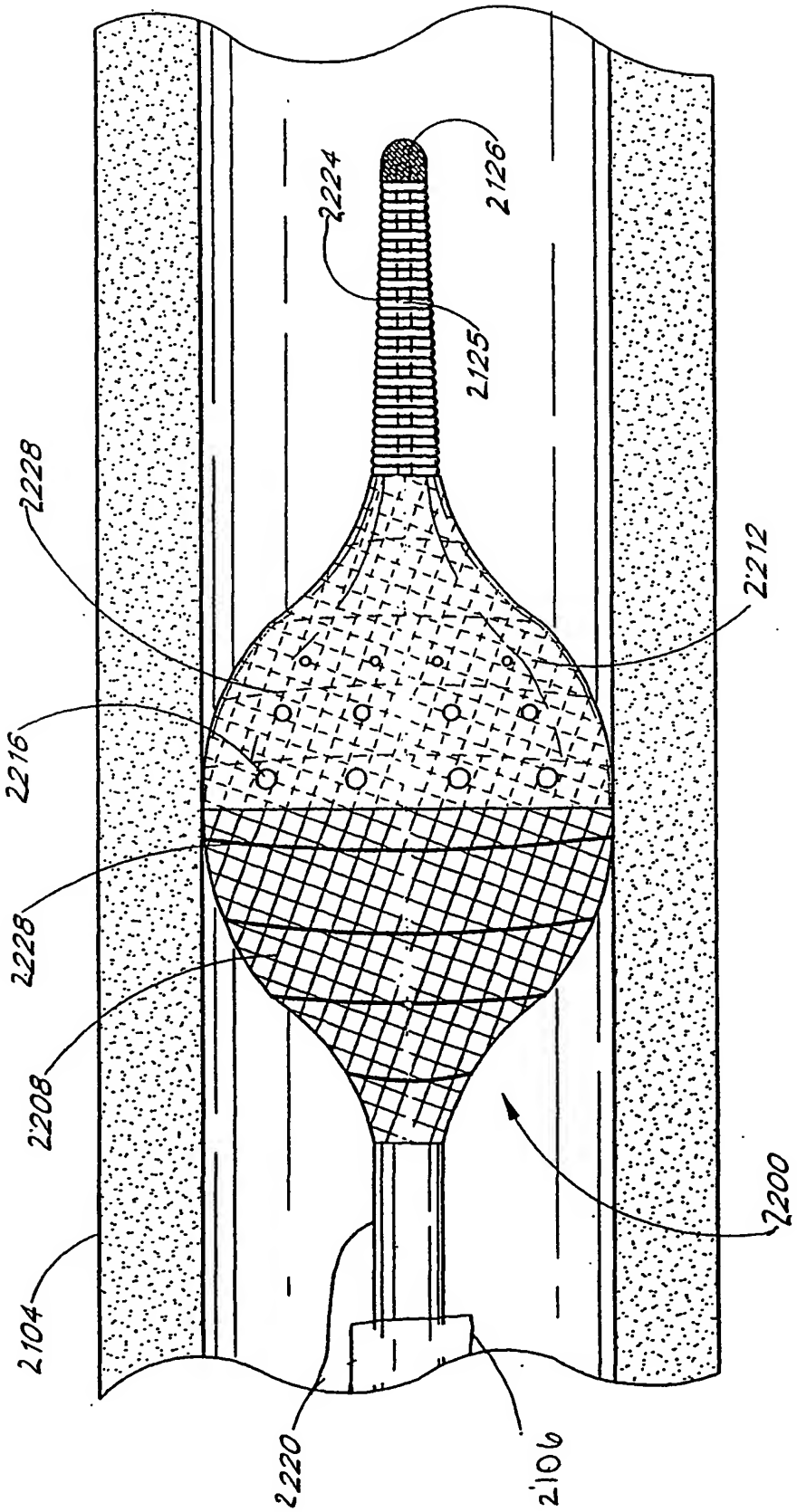

FIG. 28B

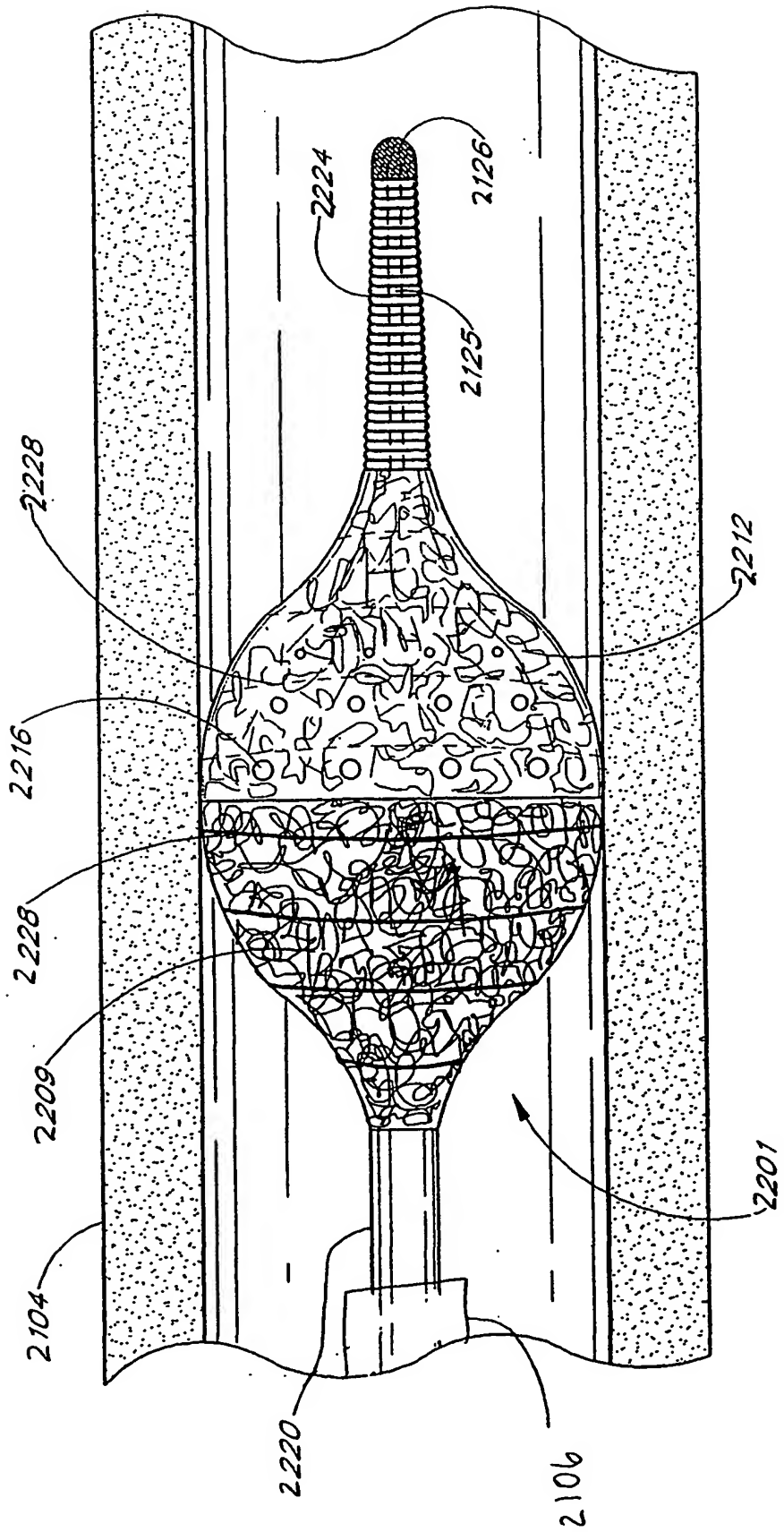

FIG. 28C

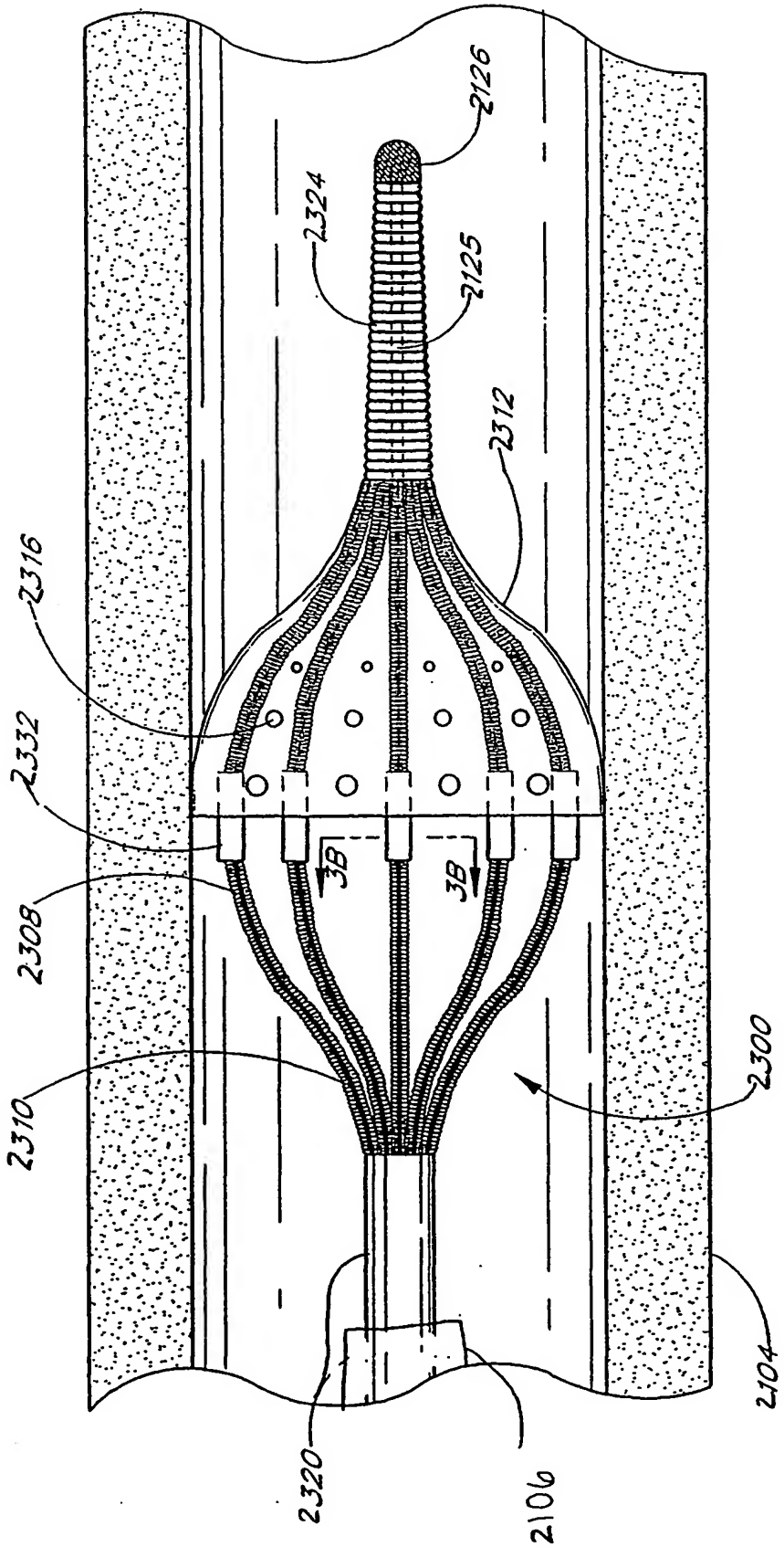

FIG. 29A

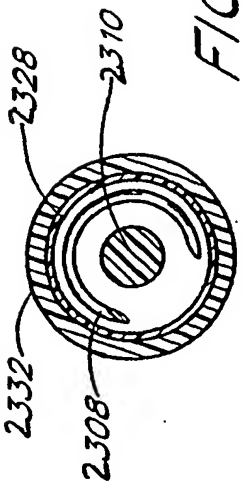

FIG. 29B

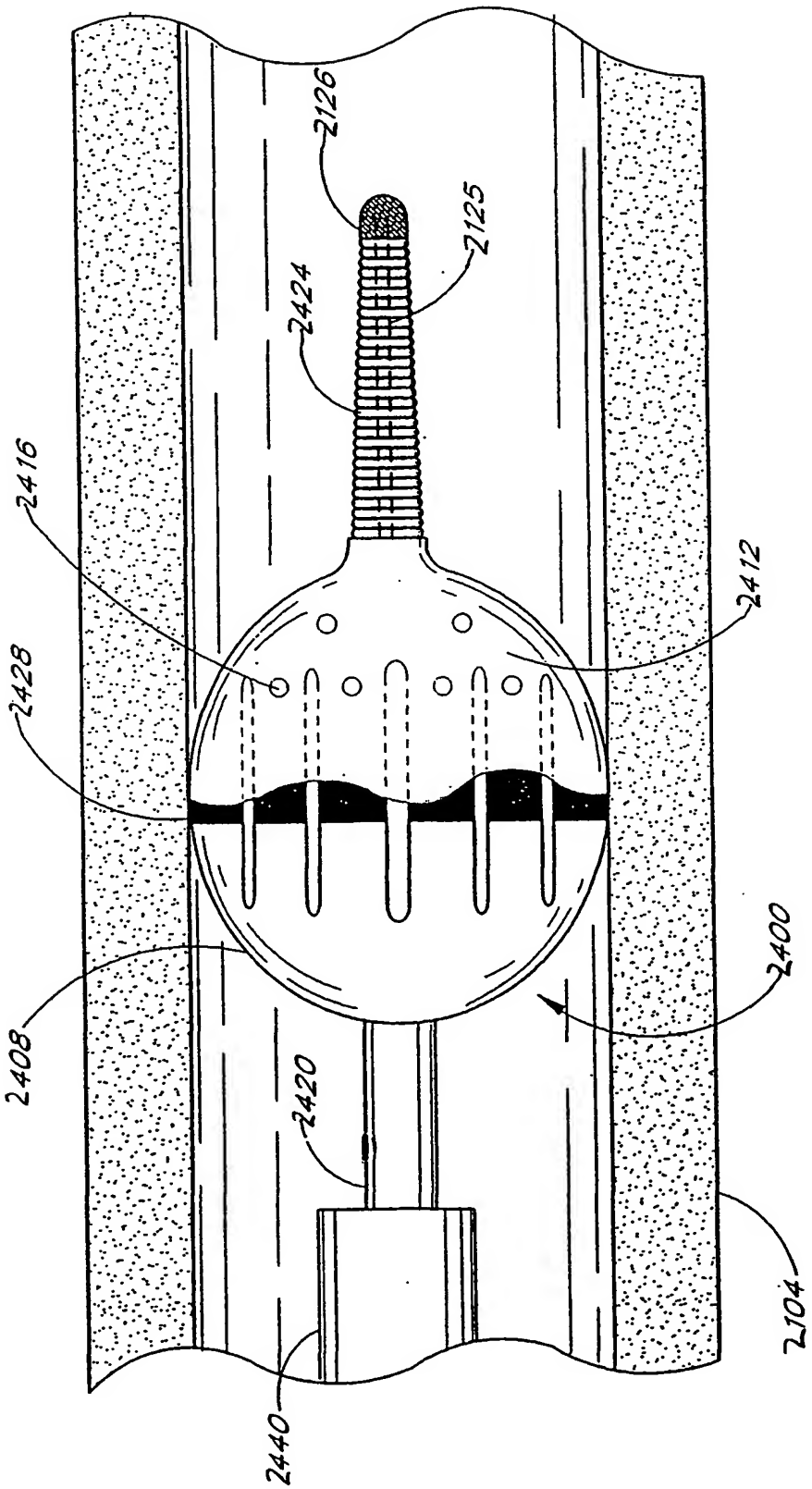

FIG. 30

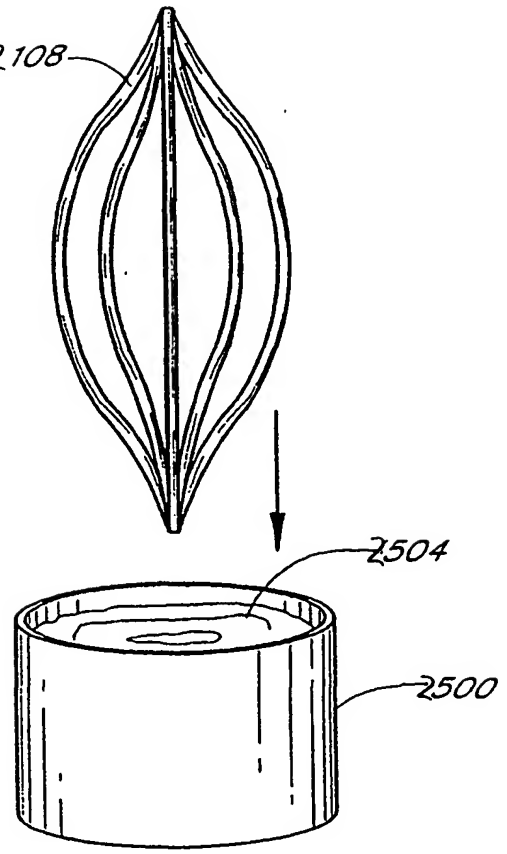

FIG. 31A

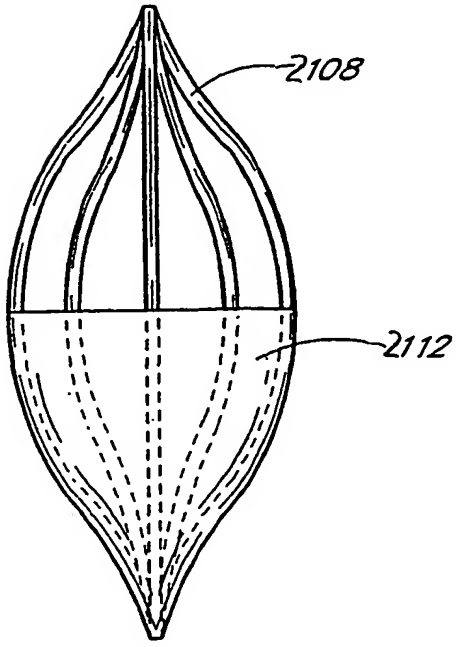

FIG. 31B

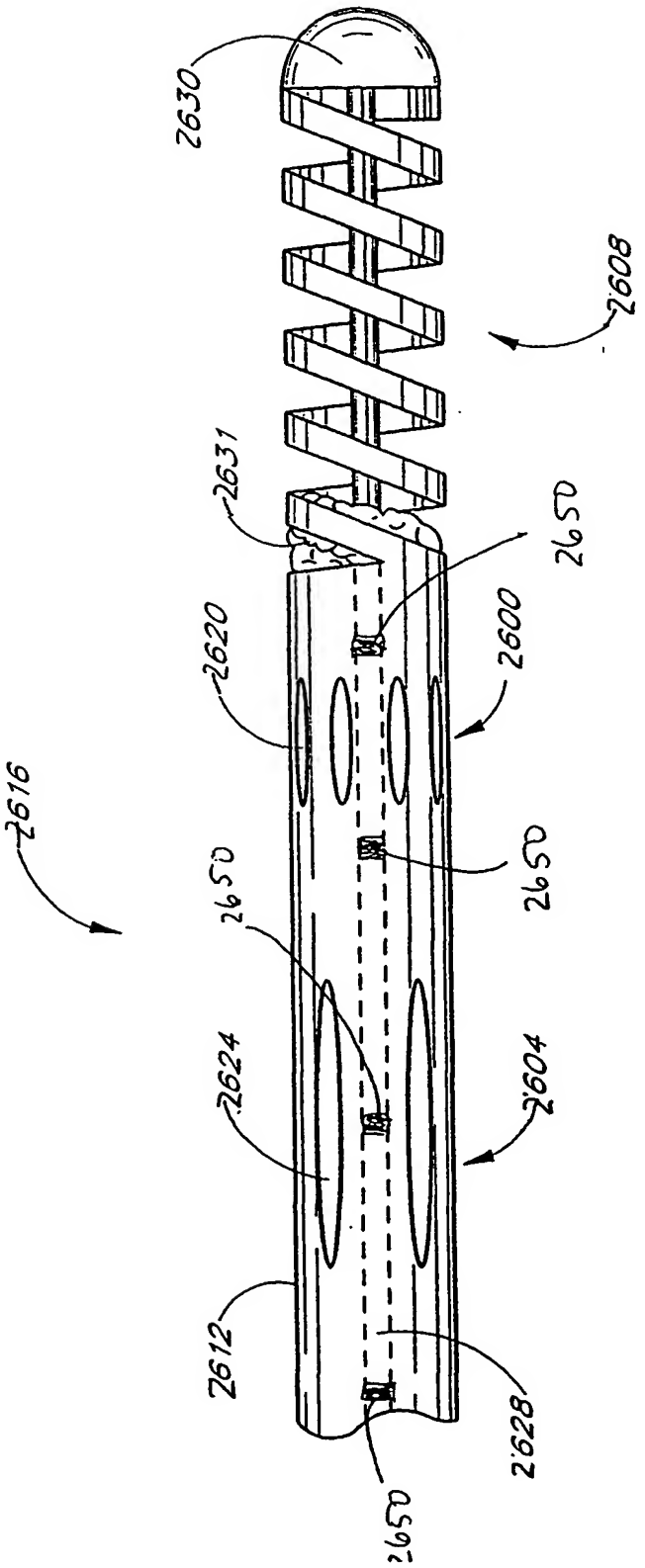
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FIG. 32

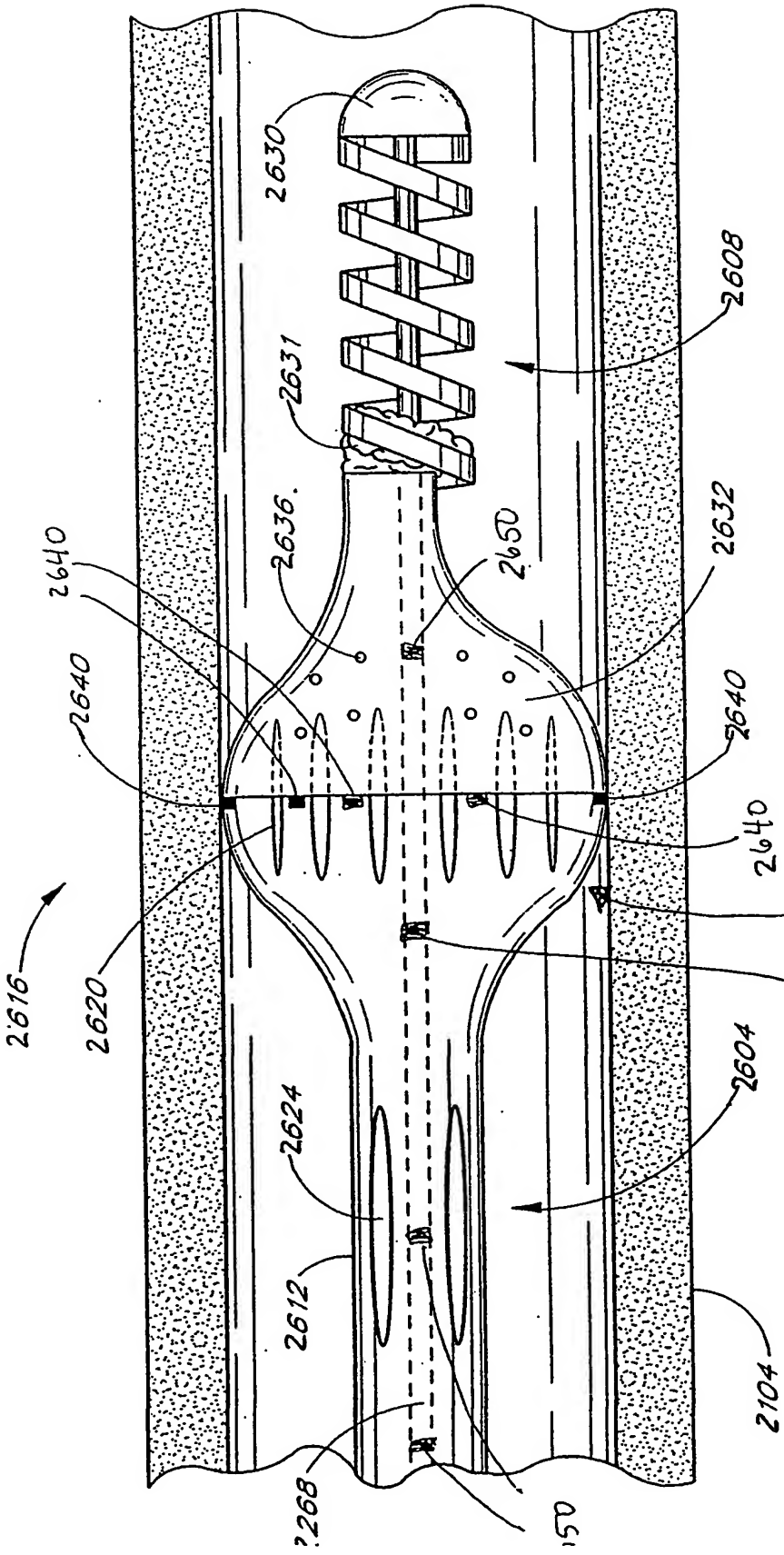
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FIG. 33

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

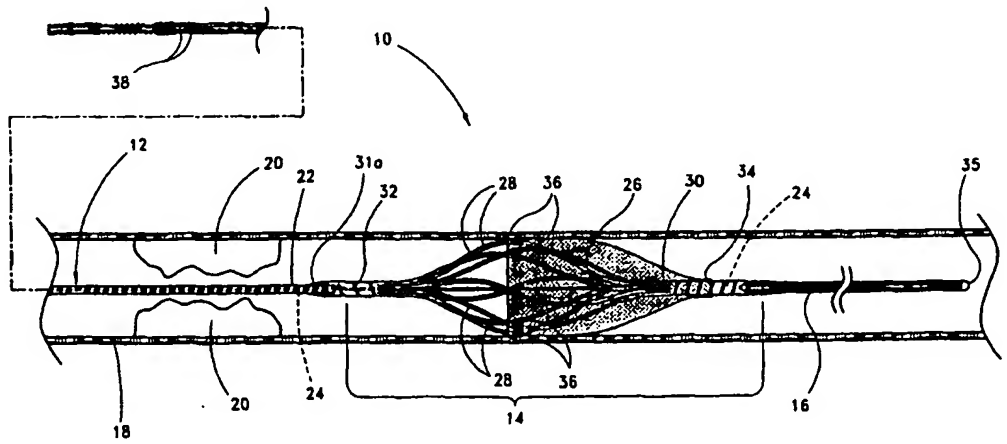
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
7 March 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STRUT DESIGN FOR AN OCCLUSION DEVICE



(57) Abstract: A filter device is inserted into the blood vessel of a patient at the end of a catheter-like shaft. The filter device includes a perfusion membrane supported by struts which are disposed distally on the shaft of the device. When actuated from an adapter located outside the patient, the struts deploy into an expanded configuration, bringing the membrane into a configuration to allow blood to pass through the filter device, but trapping embolic matter within the membrane. This embolic material is removed either by aspiration or by collapsing the struts and trapping the embolic matter within the strut system for removal along with the removal of the filter device.

WO 01/45590 A3

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 00/35157

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 99 44510 A (BIOGUIDE CONSULTING, INC.) 10 September 1999 (1999-09-10) the whole document ---	1-4,6, 19,21,22 13
Y	US 6 001 118 A (DANIEL ET AL) 14 December 1999 (1999-12-14) column 14, line 10 - line 21; figure 21A -----	13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 May 2001	10 SEP 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/US 00/35157

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-22

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22

   Occlusion device with pull wire deployment system.

2. Claims: 23-25

   A filter device with spiral cuts.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intr tional Application No
PCT/US 00/35157

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9944510 A	10-09-1999	AU 2994499 A	20-09-1999
		EP 1061856 A	27-12-2000
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		WO 9839053 A	11-09-1998
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		EP 0923344 A	23-06-1999
		US 6053932 A	25-04-2000
		WO 9838920 A	11-09-1998